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IN THE

Supreme Court of the United States

OCTOBER TERM, 1994

BARR LABORATORIES, INC.,
Petitioner,

v.

BURROUGHS WELLCOME CO.,
Respondents.

Petition for Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

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PETITION FOR WRIT OF CERTIORARI

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QUESTION PRESENTED

Whether, for purposes of 35 U.S.C. § 101, one can be the inventor of a patentable pharmaceutical method of treatment (in this instance, the use of AZT to treat AIDS) when one has no reason to believe that such method will work.

PARTIES TO THE PROCEEDING

The parties to the proceeding below were the petitioner, Barr Laboratories, Inc., the respondent, Burroughs Wellcome Co., and two other pharmaceutical manufacturing companies, Novopharm, Inc., and Novopharm Ltd. Like Barr, Novopharm, Inc. and Novopharm Ltd. were defendants in the district court and appellants in the court of appeals.

The parties before this Court are the same as those below. Barr does not know whether a petition for a writ of certiorari will be filed by Novopharm, Inc. or Novopharm Ltd.

CERTIFICATION UNDER RULE 29.1

Barr Laboratories, Inc. has no parent company. Barr has two subsidiaries, BRL Incorporated and 265 Livingston Street Corp.

TABLE OF CONTENTS

	Page
QUESTION PRESENTED	i
PARTIES TO THE PROCEEDING	ii
CERTIFICATION UNDER RULE 29.1	ii
OPINIONS BELOW	1
JURISDICTION	1
STATUTES INVOLVED	2
STATEMENT OF THE CASE	3
REASON FOR GRANTING THE WRIT	13
THE COURT OF APPEALS' VIEW OF CONCEPTION PERMITS MERE SPECULATION OR HOPE TO SUBSTITUTE FOR THE REASONABLE EXPECTATION REQUIRED BY THE PATENT LAW	13
A. The History of the Patent Law, Including the Decisions of This Court, Counsels Against the Unduly Free Granting of Patent Monopolies	13
B. The Court of Appeals' Decision Will Increase Patent Monopolies in a Manner Inconsistent With the Patent Law	14
CONCLUSION	19
APPENDIX	
A. Opinion of the Court of Appeals	1a
B. Opinion of the District Court	24a
C. Advertisement	38a

TABLE OF AUTHORITIES

CASES — Page

Alpert v. Slatin, 305 F.2d 891 (C.C.P.A. 1962) 16, 17
Amgen, Inc. v. Chugai Pharmaceutical Co., Ltd., 927 F.2d 1200, 18 U.S.P.Q. 2d 1016 (Fed. Cir. 1989), *cert. denied, sub nom. Genetics Institute, Inc. v. Amgen, Inc.*, 502 U.S. 856 (1991) 16
Atlantic Works v. Brady, 107 U.S. 192 (1882) 18
In re Barr Laboratories, Inc., 930 F.2d 72, 289 U.S. App. D.C. 187 (D.C. Cir.), *cert. denied*, 502 U.S. 906 (1991) 15
Biel v. Chessin, 347 F.2d 898, 146 U.S.P.Q. 293 (C.C.P.A. 1965) 17
Bourne v. Jones, 114 F. Supp. 413, 98 U.S.P.Q. 206 (D. Fla. 1951), *aff'd*, 207 F.2d 173 (5th Cir.), *cert. denied*, 346 U.S. 897 (1953) 16
Brenner v. Manson, 383 U.S. 519 (1966) 14, 18
Burroughs Wellcome Co. v. Barr Laboratories, Inc., 828 F. Supp. 1200 (E.D.N.C. 1993) 9
Cuno Engineering Corp. v. Automatic Devices Corp., 314 U.S. 84, 51 U.S.P.Q. 272 (1941) 18
Graham v. John Deere Co., 383 U.S. 1 (1966) 13
Great Atlantic & Pacific Tea Co. v. Supermarket Equipment Corp., 340 U.S. 147 (1950) 13, 14
Larson v. Domestic and Foreign Corp., 337 U.S. 682 (1949) 12
MacMillan v. Moffett, 432 F.2d 1237, 167 U.S.P.Q. 550 (C.C.P.A. 1970) 18
Smith v. Bosquet, 111 F.2d 157, 45 U.S.P.Q. 347 (C.C.P.A. 1940) 17
United States v. General Motors Corp., 323 U.S. 373 (1945) 12

CONSTITUTION AND STATUTES

U.S. Const. art. I, § 8, cl. 8 13
21 U.S.C. § 355(b)(1)(A) 8
21 U.S.C. § 355(j)(2)(A) 7
28 U.S.C. § 1254(1) 1, 12
28 U.S.C. § 1257 12
28 U.S.C. § 1295(a)(1) 3, 10
28 U.S.C. § 1338 3

TABLE OF AUTHORITIES—Continued

	Page
35 U.S.C. § 101	i, 2, 14
35 U.S.C. § 116	2
35 U.S.C. § 256	2, 8
35 U.S.C. §§ 261-262	16
35 U.S.C. § 271(e)(2)(A)	8
Fed. R. Civ. P. 50(a)	10
Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(j)(2)(B)	8
OTHER AUTHORITY	
1 Donald S. Chisum, Patents at OV-3 (1994)	13
3 Donald S. Chisum, Patents § 10.01 (1994)	6
Robert L. Stern, Eugene Gressman, Stephen M. Shapiro & Kenneth S. Geller, Supreme Court Practice 342-43 (7th ed. 1993)	10

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PETITION FOR WRIT OF CERTIORARI

Barr Laboratories, Inc. hereby prays that this Court grant a writ of certiorari to review the judgment of the United States Court of Appeals for the Federal Circuit in this case.

OPINIONS BELOW

The opinion of the court of appeals is reported at 40 F.3d 1223 and is reproduced in the appendix hereto. App. A, 1a. The relevant opinion of the district court is reported at 828 F. Supp. 1208 and also is reproduced in the appendix hereto. App. B, 24a.

JURISDICTION

The court of appeals denied a timely petition for rehearing on December 15, 1994. The jurisdiction of this Court is invoked under 28 U.S.C. § 1254(1).

STATUTES INVOLVED

35 U.S.C. § 101. Inventions patentable

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

35 U.S.C. § 116. Inventors

> When an invention is made by two or more persons jointly, they shall apply for patent jointly and each make the required oath, except as otherwise provided in this title. Inventors may apply for a patent jointly even though (1) they did not physically work together or at the same time, (2) each did not make the same type or amount of contribution, or (3) each did not make a contribution to the subject matter of every claim of the patent.
>
> * * *
>
> Whenever through error a person is named in an application for patent as the inventor, or through error an inventor is not named in an application, and such error arose without any deceptive intention on his part, the Commissioner may permit the application to be amended accordingly, under such terms as he prescribes.

35 U.S.C. § 256. Correction of named inventor

> Whenever through error a person is named in an issued patent as the inventor, or through error an inventor is not named in an issued patent and such error arose without any deceptive intention on his part, the Commissioner may, on application of all the parties and assignees, with proof of the facts and such other requirements as may be imposed, issue a certificate correcting such error.
>
> The error of omitting inventors or naming persons who are not inventors shall not invalidate the patent

in which such error occurred if it can be corrected as provided in this section. The court before which such matter is called in question may order correction of the patent on notice and hearing of all parties concerned and the Commissioner shall issue a certificate accordingly.

STATEMENT OF THE CASE

The human immunodeficiency virus (HIV), a retrovirus, causes acquired immune deficiency syndrome (AIDS). HIV and AIDS are to the modern world a plague as devastating as those visited upon the pharaoh of the Exodus. The first licensed drug demonstrated to be active against HIV is 3'-azido-3'-azidothymidine, commonly known as AZT.

The principal issue in this case is whether six patents (the AZT Patents) relating to the use of AZT in the treatment of those infected with HIV[1] should be corrected by adding the names of scientists employed by the National Institutes of Health (NIH) as joint inventors (sometimes referred to as "coinventors"). The jurisdiction of the court of appeals was invoked under 28 U.S.C. § 1295(a)(1) and that of the district court under 28 U.S.C. § 1338.

The respondent, Burroughs Wellcome Co. (BW), is the owner of the AZT Patents as assignee of the five BW employees named as inventors on the patents (the BW Inventors). App. A, 2a. The petitioner, Barr Laboratories, Inc. (Barr), is the licensee of the rights of NIH in the AZT Patents. App. B, 27a. NIH is a component of the U.S. Department of Health and Human Services.

If NIH has rights in the AZT Patents, then Barr can manufacture and sell a generic version of AZT in the

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[1] HIV also has been referred to as HTLV-III, LAV, and the AIDS virus.

United States. If not, then BW will remain the sole source of AZT in this country until the AZT Patents expire in 2005.

In the early 1980s, scientists like Dr. Samuel Broder of NIH began to see patients who exhibited symptoms of a disease, now known as AIDS, that attacked the patients' immune systems in a way never before seen. App. A, 3a. AIDS attacks and destroys white blood cells called CD4 T-lymphocytes, or T-cells, that constitute an important component of the human immune system. App. A, 3a. Not until mid-1984 did scientists conclude that the cause of AIDS is HIV. App. A, 3a. At about the same time, HIV first was isolated in the laboratory, enabling experimentation with the live retrovirus and meaningful searches for potential drug therapies. Experimentation with live HIV is dangerous and requires special laboratory facilities to minimize the risk of infection.

Dr. Broder, assisted by Dr. Hiroaki Mitsuya of NIH, stepped up his previous efforts to identify an effective AIDS therapy. After several attempts, Broder and Mitsuya created a unique line of cells, called the ATH8 cell line, that could be used to demonstrate a chemical compound's effectiveness against HIV in humans.[2] App. A, 4a. Broder and Mitsuya began seeking compounds from private drug manufacturers for complex technical testing using the ATH8 cell line. App. A, 4a.

BW, a private drug manufacturer, began its own search for an AIDS treatment in June 1984. App. A, 3a. BW was unable to work with live HIV and therefore sought collaborations with outside researchers who were able and willing to work with the live virus. BW first contacted researchers at Duke University, one of whom introduced Dr. Broder of NIH to the BW team. BW in-

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[2] Broder and Mitsuya received a patent on the ATH8 cell line in 1987.

vited Broder to conduct a seminar at BW in early October 1984. On that occasion Broder and one of the BW Investors agreed that Broder would accept "candidate" compounds from BW for testing against live HIV.

Unlike Broder and Mitsuya, BW did not work with live HIV but instead screened compounds against two *mouse* retroviruses that did not present a risk of infection to humans. App. A, 3a-4a. Barr offered to prove at trial that the activity of a compound against the mouse screens is not predictive of the compound's activity against a *human* retrovirus such as HIV, that as a result BW used the mouse screens merely to generate a pool of candidate compounds, and that the mouse tests did not give—and could not have given—the BW Inventors a reasonable belief that AZT would work against HIV. App. B, 31a. As is discussed more fully below, Barr's evidence was excluded as irrelevant after the district court ruled that one can conceive an invention without any belief that the item or process will work in practice (or even if one believes that the item or process will *not* work in practice).

By early November 1984 the BW Inventors had tested 113 compounds, screened from its considerable inventory of substances shown to be nontoxic in mass toxicology and pharmacology testing. BW decided to submit eighteen of these to outside scientists. In mid-November 1984 one of the BW Inventors observed that AZT was active against the mouse retrovirus. BW thereupon added AZT to the list of compounds to be tested by the outside researchers at Duke as well as by researchers at the Food and Drug Administration. Eighteen compounds were sent to Duke and the FDA.

Despite BW's favorable results against the mouse screens, the testing of AZT at Duke and the FDA during December 1984 and January 1985 did not yield positive results in human cell lines infected with HIV.

Some results were equivocal as to whether AZT was active against HIV replication, others showed no such activity, and still others indicated that AZT was toxic to human cells.

BW prepared draft, boilerplate United Kingdom patent applications for a number of the eighteen compounds, assigning AZT the lowest priority level among all BW's then-projected filings. BW traditionally files patent applications first in its home country, the United Kingdom. Unlike the United States, which gives priority to the first person to *invent*, the United Kingdom gives priority to the first person to *file* a patent application. *See* 3 DONALD S. CHISUM, PATENTS § 10.01 (1994) (CHISUM). For this reason there is an extraordinary premium on filing quickly in the United Kingdom and hence on preparing a U.K. application whenever there is the slightest suggestion that a patentable item or process might conceivably be on the horizon, even if the evidence is grossly insufficient to constitute conception.

BW did not file the AZT patent application at that time, even in the United Kingdom. BW did not take such additional steps as instituting clinical trials of AZT. Barr was denied the opportunity to prove at trial that despite the routine preparation of draft United Kingdom patent applications for AZT and other compounds around the beginning of February 1985, the BW Inventors had no reason to believe (and evinced no belief) at that time that AZT would be effective against HIV or AIDS.

On February 4, 1985 BW, which previously had sent Dr. Broder five compounds for testing against HIV in the ATH8 cell line, sent him AZT identified as Compound S. App. A, 4a. Doctors Broder and Mitsuya tested the BW compounds, using tests that BW itself had neither the expertise nor the facilities to perform. Broder and Mitsuya found AZT activity against the live AIDS virus at various concentrations, thus becoming the first to discover that AZT is active against the live AIDS virus.

On February 20, 1985 Broder informed one of the BW Inventors that the NIH experiments had shown that AZT is active against HIV. In the words of one of the BW Inventors, "[t]hings really began to move incredibly fast" once Dr. Broder's news reached BW. In the words of a BW internal newsletter, "[t]he green light was on."

BW did not overlook the enormous financial potential of AZT, either. An internal BW memo, dated April 15, 1985, noted that "[m]arket penetration would be complete with little promotional effort because of the usually fatal nature of the illness" and that "[a] *premium price* could be obtained * * * [I]f one assumes a moderate *premium* price of $10 a day for 1 year for only 10% of all infected patients, sales would be nearly $150 million for that year" (emphasis added). BW filed its patent application in the United Kingdom on March 16, 1985. App. A, 5a.

Thereafter, during clinical trials of AZT, Dr. Broder and another NIH researcher, Dr. Robert Yarchoan, conducted a patient study showing that treatment with AZT could increase a patient's T-cell count. Dr. Broder reported this to one of the BW Inventors in late July 1985. App. A, 5a.

BW (as assignee of the BW Inventors) filed its initial United States patent application on September 17, 1985. App. A, 2a. All the AZT Patents ultimately flowed from that application. Neither that application nor any other submission made to the U.S. Patent and Trademark Office named as coinventor (or even mentioned) Dr. Broder, Dr. Mitsuya, or Dr. Yarchoan. The AZT Patents were issued to BW at various times between October 1987 and June 1989. App. A, 2a n.2.

In March 1991 Barr filed an abbreviated new drug application (ANDA)[3] with the FDA seeking approval

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[3] Generic drugs must be shown to contain the same active ingredients as brand drugs and to be "bioequivalent" to such drugs. 21 U.S.C. § 355(j)(2)(A). Because the safety and efficacy of the

to manufacture and sell a generic version of AZT. This filing constituted a technical infringement of the AZT Patents. 35 U.S.C. § 271(e)(2)(A). As required by the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(j)(2)(B), Barr notified BW of Barr's submission of the ANDA. On May 14, 1991 BW filed this patent infringement suit against Barr in the U.S. District Court for the Eastern District of North Carolina.

NIH believed that Dr. Broder and his colleagues should have been named as coinventors of the AZT Patents. On July 11, 1991 NIH granted Barr a nonexclusive license to sell AZT and authorized Barr to litigate the government's inventorship dispute with BW. Barr agreed to pay the government a royalty on all commercial sales of AZT. Barr stated publicly that the sales price of Barr's version of AZT would be substantially lower than that being charged by BW.

Among Barr's counterclaims was one for correction of the AZT Patents to list Dr. Broder and his colleagues as joint inventors. 35 U.S.C. § 256. Barr's position was and is that the coinvention of the AZT Patents by federal employees made the federal government an owner of the AZT Patents and that by virtue of the NIH license to Barr, Barr's manufacture and sale of AZT would not infringe those patents.[4]

BW denied that Doctors Broder, Mitsuya, and Yarchoan were coinventors of any of the AZT Patents. BW

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drug previously has been demonstrated in connection with the brand manufacturer's new drug application (NDA), 21 U.S.C. § 355(b)(1)(A), it need not be shown again for the generic version.

[4] Novopharm Ltd., which is not affiliated with Barr, later filed its own ANDA for AZT. BW's suit against Novopharm Ltd. and its U.S. affiliate, Novopharm, Inc. (collectively, Novopharm), for patent infringement was joined with the BW-Barr action. Novopharm, which does not hold a license from NIH, takes the position that BW's failure to list the NIH scientists as coinventors (1) renders the patents invalid and (2) constituted inequitable conduct that makes the patents unenforceable.

also contended that the doctrines of laches, estoppel, and waiver barred the assertion by these individuals—or the federal government—of any rights in the AZT Patents.

At trial Barr sought to demonstrate that (1) the activity or inactivity of AZT against the mouse retroviruses was not predictive of activity against HIV, (2) the BW Inventors were well aware of this infirmity of the BW mouse screens, and (3) the results of the testing at Duke and the FDA had been disappointing at best. This would permit the jury to find that in early February 1985, when BW prepared the draft U.K. patent application and sent AZT to NIH for testing against live HIV, the BW Inventors had no reason to believe or expect that AZT would be active against HIV. Barr wanted jury instructions that in the highly experimental and uncertain scientific area involved in the development of drugs, conception does not occur until and unless an inventor has a reasonable expectation that the invention will work in practice, and that if the jury found that the BW scientists did not have such an expectation when BW sent AZT to NIH for testing, the NIH scientists should be listed as coinventors. The district court, however, had rejected the "reasonable expectation" and the "simultaneous conception and reduction to practice" approaches before jury instructions were submitted. *See* App. B, 30a; *Burroughs Wellcome Co. v. Barr Laboratories, Inc.*, 828 F. Supp. 1200, 1205 (E.D.N.C. 1993) (denying summary judgment motions).

"Conception" (for purposes of making one an inventor) has two elements. The first element is a definite and permanent idea of the complete and operative invention as it is to be applied in practice. App. B, 30a. The second is the definition and preservation of the inventor's idea in a manner (typically written) that enables one of ordinary skill in the art to reduce the invention to practice. App. B, 30a-31a. The district court correctly recognized that the focus of the dispute between Barr/NIH and BW is on the first element. App. B, 31a.

The district court ruled, however, that "so long as the [inventor's] idea is sufficiently defined and preserved, the law does not require that the inventor's idea be reasonable, scientifically accurate, or capable of being proved." App. B, 30a. Accordingly, the district court refused to let Barr demonstrate that the BW Inventors did not have a reasonable belief that AZT would work against the HIV virus before the BW Inventors heard the results of the tests conducted by Dr. Broder and Dr. Mitsuya. Having reached this conclusion, the district court granted BW's motion for judgment as a matter of law, FED. R. CIV. P. 50(a), stating that the BW Inventors had conceived of the subject matter of the inventions embodied in all six of the AZT Patents at some time *before* AZT was sent to Dr. Broder on February 6, 1985. App. B, 32a-33a.[5]

Barr appealed to the Court of Appeals for the Federal Circuit. 28 U.S.C. § 1295(a)(1). There Barr pointed out that the standard applied by the district court requires nothing more for conception than someone's thinking that somewhere in a warehouse full of identified compounds is one that may turn out to be effective against one of dozens of identified diseases. At least in the unpredictable

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[5] The district court also denied Barr's motion for partial summary judgment on the issue of whether estoppel, laches, or waiver could be invoked against a property right claimed by the United States. App. B, 34a-36a. The court found "no basis for finding [sufficient to grant a motion for summary judgment] that the government has a constitutionally-protected property interest in the [AZT Patents]" but went on to say that "[w]hether these equitable doctrines can be applied in this case is a question that cannot be decided as a matter of law. This ruling in no way expresses any opinion as to whether the elements of these doctrines can be satisfied in this case based upon the evidence." App. B, 36a. Barr raised this issue before the court of appeals, which mentioned the issue in passing, App. A, 5a-6a, but did not further address it. Accordingly, Barr has not raised the issue in this petition, *see* ROBERT L. STERN, EUGENE GRESSMAN, STEPHEN M. SHAPIRO & KENNETH S. GELLER, SUPREME COURT PRACTICE 342-43 (7th ed. 1993) (STERN & GRESSMAN), but expects to renew the issue below when appropriate.

area of treatment of the human body, Barr stated, "the standard would reward the generation of a lengthy candidate compounds list and would deny inventorship to those who make the crucial and often inventive contribution necessary to narrow the field of candidate compounds to a list of actually useful compounds."

The court of appeals affirmed the legal conclusion of the district court, remanding one of the AZT Patents to the district court but sustaining the finding of BW ownership of the other five. App. A, 13a-19a. The court said that the "definite and permanent idea" required for conception meets that standard "when the inventor has a specific, settled, idea, a particular solution to the problem at hand, not just a general goal or research plan he hopes to pursue," App. A, 9a, but that "[a]n inventor's belief that his invention will work [is] irrelevant to conception." App. A, 10a. Apparently agreeing with the district court, the court continued that this is so even "when the invention deals with uncertain or experimental disciplines, where the inventor cannot reasonably believe an idea will be operable until some result supports that conclusion." App. A, 9a-10a.

Based upon the foregoing statement of what it viewed as the law, the court of appeals rejected the idea that an inventor in an uncertain field must have some basis for believing that his "invention" will work. App. A, 9a-11a. Confusingly, the court then said that "[a] conception is not complete if the subsequent course of experimentation, especially experimental failures, reveals uncertainty that so undermines the specificity of the inventor's idea that it is not yet a definite and permanent reflection of the complete invention as it will be used in practice." App. A, 11a-12a. Thus the court said, almost in the same breath, that conception is *completed* before there is any notion as to whether an invention will work *and* that if subsequent experimentation undermines the idea, conception has *not* occurred. These two statements are inconsistent and leave

the scientific community without a clear standard as to what constitutes conception in the fields of chemistry and biology.

The court of appeals affirmed the district court's decision as to five of the six AZT Patents, stating that "[w]hether or not Burroughs Wellcome believed the inventions would in fact work based on the mouse screens is irrelevant." App. A, 16a. As to the remaining patent, the court said that the record was inconclusive on whether conception of the increase-of-T-cell-count idea had occurred before the clinical trials were conducted at NIH by Doctors Broder and Yarchoan. App. A, 16a-19a. Accordingly, the decision as to that patent was vacated and remanded for further proceedings. App. A, 19a.[6]

Circuit Judge Lourie filed a separate opinion, stating that the majority's opinion confused the ideas of conception, corroboration, and reduction to practice. App. A, 20a. He agreed with the decision on five of the patents but disagreed with the remand of the sixth, stating that its method "is an inherent, inevitable result of the practice of the other [AZT Patents]" and hence cannot be separated from them. App. A, 21a.

Novopharm sought rehearing on the ground that the experimental failures at Duke and the FDA came within

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[6] This remand for further factual development regarding one of the six patents technically deprives the judgment below of finality. That fact should not preclude review now by this Court. First, finality is a prudential matter rather than a jurisdictional requirement where the judgment to be reviewed is that of a federal court. *Compare* 28 U.S.C. § 1254(1) (authorizing Supreme Court review of "[c]ases in the courts of appeals . . . before or after rendition of judgment or decree") *with* 28 U.S.C. § 1257 (limiting Supreme Court review of state court decisions to "[f]inal" judgments). Further, the decision below *is* final as to the only issue likely to command the attention of this Court—whether one can conceive of an invention for patent purposes when one has no idea whether the invention will work. *See, e.g., Larson v. Domestic & Foreign Corp.*, 337 U.S. 682, 685 n.3 (1949); *United States v. General Motors Corp.*, 323 U.S. 373, 377 (1945).

the court of appeals' statement that conception may be incomplete if subsequent experimental failures occur. Accordingly, Novopharm stated, the district court's grant of judgment as a matter of law in favor of BW was incorrect and reversal of the decision below was in order. Rehearing was denied, without opinion, on December 15, 1994.

REASON FOR GRANTING THE WRIT

THE COURT OF APPEALS' VIEW OF CONCEPTION PERMITS MERE SPECULATION OR HOPE TO SUBSTITUTE FOR THE REASONABLE EXPECTATION REQUIRED BY THE PATENT LAW.

A. The History of the Patent Law, Including the Decisions of This Court, Counsels Against the Unduly Free Granting of Patent Monopolies.

Our patent law flows from the Constitution: Congress is authorized "To promote the Progress of . . . useful Arts, by securing for limited Times to . . . Inventors the exclusive Right to their . . . Discoveries." U.S. CONST. art. I, § 8, cl. 8. While the Patent Clause appears among the Constitution's grants of power to the Congress, its limitations reflect the Framers' hostility to unearned monopolies. *Graham v. John Deere Co.*, 383 U.S. 1, 5-10 (1966). Thomas Jefferson, the author of the 1793 Patent Act [7] and a renowned inventor, "had an instinctive aversion to monopolies." *Id.* at 7. Though he eventually came to accept the idea of limited patent monopolies, he did so not because he believed inventors should have exclusive rights to their inventions but because "[t]he patent monopoly . . . was a reward, an inducement, to bring forth new knowledge. The grant of an exclusive right to an invention was the creation of society—at odds with the inherent free nature of disclosed ideas—and was not to be freely given." *Id.* at 9. "The Framers plainly did not want [patent] monopolies freely granted." *Great Atlantic*

[7] The concepts underlying the 1793 statute remain fundamental features of our patent law today. 1 CHISUM, at OV-3.

& Pacific Tea Co. v. Supermarket Equipment Corp., 340 U.S. 147, 154 (1950) (Douglas, J., concurring).

Only one month after deciding *Graham*, this Court offered an illuminating example of the *limited* nature of the patent monopoly. Addressing the patentability of a chemical process, the Court wrote that the requirement that an invention be "useful" to be patentable, 35 U.S.C. § 101, does not mean merely that the process be non-detrimental or worthy of study. *Brenner v. Manson*, 383 U.S. 519 (1966). Instead, the patent statute is to be read narrowly, to authorize the issuance of a patent and the creation of a monopoly "only if clearly commanded" by its text. *Id.* at 534.

> Until the process claim has been reduced to production of a product shown to be useful, the metes and bounds of that monopoly are not capable of precise delineation. It may engross a *vast, unknown, and perhaps unknowable area.* Such a patent may confer a power to block off *whole areas of scientific development,* without compensating benefit to the public.

Id. (emphasis added). The Court concluded by noting that "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion." *Id.* at 536.

B. The Court of Appeals' Decision Will Increase Patent Monopolies in a Manner Inconsistent With the Patent Law.

"The attempts through the years to get a broader, looser conception of patents than the Constitution contemplates have been persistent." *Great Atlantic & Pacific*, 340 U.S. at 156 (Douglas, J., concurring). Regrettably, the court of appeals has yielded in the instant case to the temptation described by Justice Douglas.

The court of appeals' has departed from existing law in a way that tips the scales significantly in favor of the

brand pharmaceutical industry, with its monopoly prices, and against the generic drug industry, which operates in the free market. The difference can be significant:

> [F]or poorer people—the users for whom access to generic drugs is most important—a pecuniary saving on drugs may have important health benefits. The difference between sinking, say, 3% and 20% of one's income into pharmaceuticals spells a large difference in the range of economically accessible food and shelter.

In re Barr Laboratories, Inc., 930 F.2d 72, 75, 289 U.S. App. D.C. 187, 190 (D.C. Cir.), *cert. denied*, 502 U.S. 906 (1991).

The decision below also is likely to affect the important role of NIH in developing new pharmaceutical products. If NIH continues its past practice of cooperation with the private sector, the court of appeals' bias in favor of finding conception at the earliest possible time will mean that taxpayers' funds will go to provide private drug manufacturers with monopoly pricing opportunities. If, on the other hand, NIH decides to cease participating in an exercise that enriches private manufacturers at the expense of the public treasury, efforts to find new drugs likely will be hampered significantly.

The cases discussed above reflect this Court's recognition that the presumption of our patent code is against the grant of patent monopolies. The case at bar is analogous and the same principle should be applied here. This time the defect of the decision below is not in permitting patenting in the absence of utility, which this Court barred in *Manson*, or in the absence of novelty, which this Court barred in *Great Atlantic & Pacific* and other cases. Here the error is in the invitation to become an inventor by claiming that any number of identified compounds will cure any number of identified diseases. No matter how many compounds or diseases are named, and no matter how little faith the namer has that *any* of the

named compounds will cure *any* of the named diseases, the namer will be the inventor of a patentable process if *any* of the compounds turns out to cure *any* of the diseases. That is the import of the decision below.

Where a patent has joint inventors, each (or his assignee) is the owner of the patent and may practice the patent without the permission of his coinventors. 35 U.S.C. §§ 261-262. Thus an approach that minimizes the number of joint inventors will contribute to patent monopolization. The facts of this case are instructive. Consistent with the marketing memorandum discussed above, BW initially made the most of its monopoly by charging as much as $10,000 per year per patient for AZT. This amount later was reduced under intense public pressure. By contrast, NIH, which often performs the role it did in this case, has granted a *non*exclusive license to Barr. Barr in turn has promised to sell AZT for considerably less than BW. Further, should the joint inventorship of the NIH scientists be recognized, NIH will retain the right to license drug companies in addition to Barr to produce AZT.

Conception requires more than a mere hope or expectation, *Alpert v. Slatin*, 305 F.2d 891, 894 (C.C.P.A. 1962), and more than "mere speculation or . . . probable deduction from facts already known," *Amgen, Inc. v. Chugai Pharmaceutical Co., Ltd.*, 927 F.2d 1200, 1207, 18 U.S.P.Q.2d 1016, 1021 (Fed. Cir. 1989) (interior quotation marks omitted), *cert. denied, sub nom. Genetics Inst., Inc. v. Amgen, Inc.*, 502 U.S. 856 (1991). It must be "based on something ascertained, something definite and certain." *Bourne v. Jones*, 114 F. Supp. 413, 418, 98 U.S.P.Q. 206, 209 (D. Fla. 1951), *aff'd*, 207 F.2d 173 (5th Cir.), *cert. denied*, 346 U.S. 897 (1953).

In most patent cases the reasonable expectation of the inventor is not at issue. Most cases do not arise in highly experimental or uncertain areas. Typically there is existing knowledge that itself provides a reasonable expecta-

tion that a new idea will work. Where the invention arises in an area about which little is known, though, the reasonable expectations of the inventor are properly an issue. The predecessor of the Court of Appeals for the Federal Circuit recognized this thirty years ago, stating that where the invention is "a method of treating the human body . . ., conception thereof is a far different thing than merely thinking of the use of the compound. There must be some concomitant reasonable understanding or appreciation of the fact that the compound would work and in what way." *Biel v. Chessin*, 347 F.2d 898, 902-03, 146 U.S.P.Q. 293, 296-97 (C.C.P.A. 1965) (Rich, J.). So the law used to be, but the decision in the case at bar brushed off the *Biel* standard as dictum.

The court of appeals all but ignored the line of cases relating to simultaneous conception and reduction to practice. This doctrine is applied to situations "where results at each step do not follow as anticipated, but are achieved empirically by what amounts to trial and error." *Alpert*, 305 F.2d at 894, 134 U.S.P.Q. at 299; *see Smith v. Bosquet*, 111 F.2d 157, 45 U.S.P.Q. 347 (C.C.P.A. 1940). For this reason, there in effect *cannot* be conception until the invention has been shown to work. The experimental failures of AZT in the Duke and FDA trials exemplify the circumstances in which this doctrine applies, but the court of appeals brushed off this idea as well. App. A, 11a-12a.

By way of example, a drug company uninvolved in this case recently advertised that it had tested 3000 compounds before discovering one that worked against life-threatening infections, and that thereafter it tested 27,000 more "to ensure that [it] had the best one." App. C, 38a.[8] Under the decision below, the company reached the point of conception as to at least 3000, and arguably as many as 30,000, compounds at the moment the compounds initially were selected for testing. Such is not the law.

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[8] The advertisement is not part of the record.

To summarize, the court of appeals has said in this case that even in the uncertain field of human biology and chemistry, a researcher who has no expectation or belief that his idea will work nevertheless is the inventor. The same court, which hears all appeals in patent cases, previously has indicated that there is no limit on the number of compounds that one can contend will act against a disease. *MacMillan v. Moffett*, 432 F.2d 1237, 167 U.S.P.Q. 550 (C.C.P.A. 1970). The invitation to abuse is unmistakable. Like the broad, open-ended approach to the requirement of utility that this Court rejected in *Manson*, the approach of the court of appeals to conception here "may engross a vast, unknown, and perhaps unknowable area. Such a patent may confer a power to block off whole areas of scientific development, without compensating benefit to the public." *Manson*, 383 U.S. at 534.

More than a century ago this Court warned unanimously against "the indiscriminate creation of exclusive [patent] privileges" as a course that tends to obstruct rather than stimulate invention. *Atlantic Works v. Brady*, 107 U.S. 192, 200 (1882); *accord Cuno Eng'g Corp. v. Automatic Devices Corp.*, 314 U.S. 84, 92, 51 U.S.P.Q. 272, 276 (1941). "It was never the object of [the patent] laws," wrote Justice Bradley, "to grant a monopoly for . . . every shadow of a shade of an idea." *Brady*, 107 U.S. at 200.

In *Brady*, and later in *Cuno* and *Great Atlantic & Pacific*, this Court demanded substantial novelty as a prerequisite for a patent. In *Manson* this Court demanded practical utility as a prerequisite for a patent. Today this Court faces the choice between a loose and a rigorous standard of conception. The loose standard, adopted by the court of appeals, permits a researcher to "conceive" a method of treatment simply by declaring that somewhere in a potentially limitless list of compounds is one that will counteract one of a potentially limitless

list of diseases. The rigorous standard, which this Court should adopt, requires at least a reasonable belief or expectation that the proposed method will work in practice. This Court should grant the writ and then recognize the rigorous standard as correct.

CONCLUSION

If not reviewed by this Court, the court of appeals' view of what constitutes conception in an uncertain or experimental field of scientific endeavor will permit mere speculation or hope to substitute for the more concrete level of certainty required by the patent law. This allows conception based upon research plans rather than upon true inventions—a result that is inconsistent with the patent law as well as with common sense. The result below will enhance monopoly drug pricing and either discourage the NIH from cooperating with the private sector in developing new drugs or result in the expenditure of tax money to benefit monopolists. A writ of certiorari should issue to review the judgment of the Court of Appeals for the Federal Circuit.

Respectfully submitted,

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March 1995

APPENDIX A

UNITED STATES COURT OF APPEALS
FEDERAL CIRCUIT

Nos. 93-1503 to 93-1505

BURROUGHS WELLCOME CO.,
Plaintiff-Appellee,

v.

BARR LABORATORIES, INC.,
Defendant-Appellant,

and

NOVOPHARM, INC. and NOVOPHARM, LTD.,
Defendants-Appellants.

Nov. 22, 1994

Rehearing Denied Dec. 15, 1994

Before MAYER, LOURIE, and SCHALL, Circuit Judges.

MAYER, Circuit Judge.

Barr Laboratories, Inc., Novopharm, Inc., and Novopharm, Ltd., appeal the order of the United States District Court for the Eastern District of North Carolina, *Burroughs Wellcome Co. v. Barr Lab., Inc.*, 828 F.Supp. 1208 (E.D.N.C.1993), granting the motion of Burroughs Wellcome Co. for judgment as a matter of law that six United States patents were not invalid and were infringed. We affirm in part, vacate in part, and remand.

Background

Burroughs Wellcome Co. is the owner of six United States patents that cover various preparations of 3'-azidothymidine (AZT) and methods for using that drug in the treatment of persons infected with the human immunodeficiency virus (HIV).[1] Each of these patents names the same five inventors—Janet Rideout, David Barry, Sandra Lehrman, Martha St. Clair, and Phillip Furman (Burroughs Wellcome inventors)—all of whom were employed by Burroughs Wellcome at the time the inventions were alleged to have been conceived. The defendants-appellants concede that all five are properly named as inventors on the patents.

Burroughs Wellcome's patents arise from the same parent application filed on September 17, 1985.[2] Five of the patents relate to the use of AZT to treat patients infected with HIV or who have acquired immunodeficiency syndrome (AIDS).[3] The other patent, the '750 patent, covers

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[1] Although two of the patents claim pharmaceutical compositions of AZT, not methods of treatment per se, the parties treat all of the patents as covering the particular use of AZT as a treatment for AIDS and its symptoms. The district court adopted this interpretation and applied the patents as though all claimed methods of treatment; no party argues for another interpretation, so we do the same.

[2] The following patents are at issue: U.S. Patent No. 4,724,232 (the '232 patent), filed September 17, 1985, issued February 9, 1988; No. 4,828,838 (the '838 patent), filed October 21, 1987, issued May 9, 1989; No. 4,833,130 (the '130 patent), filed October 20, 1987, issued May 23, 1989; No. 4,837,208 (the '208 patent), filed October 20, 1987, issued June 6, 1989; No. 4,818,538 (the '538 patent), filed October 21, 1987, issued April 4, 1989; and No. 4,818,750 (the '750 patent), filed October 20, 1987, issued April 4, 1989.

[3] Claim 1 of the '232 patent covers "[a] method of treating a human having acquired immunodeficiency syndrome comprising the oral administration of an effective acquired immunodeficiency syn-

a method of using AZT to increase the T-lymphocyte count of persons infected with HIV.[4]

In the early 1980s, scientists began to see patients with symptoms of an unknown disease of the immune system, now known as AIDS. The disease attacks and destroys certain white blood cells known as CD4 T-lymphocytes or T-cells, which form an important component of the body's immune system. The level of destruction eventually becomes so great that the immune system is no longer able to mount an effective response to infections that pose little threat to a healthy person.

In mid-1984, scientists discovered that AIDS was caused by a retrovirus, known as HTLV III or, more commonly today, HIV. After the identification of HIV, Burroughs Wellcome began to search for a cure, screening compounds for antiretroviral activity using two murine

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drome treatment amount of 3'-azido-3'-deoxythymidine to said human."

Claim 1 of the '838 patent covers "[a] pharmaceutical preparation comprising a capsule containing 5 to 500 mg of 3'-azido-3'-deoxythymidine."

Claim 1 of the '130 patent covers "[a] method of treating a human having an HTLV III virus infection comprising administering to said human an effective HTLV III virus treatment amount of 3'-azido-3'-deoxythymidine."

Claim 1 of the '208 patent covers "[a] method of treating a human having antibodies to the HTLV III virus which comprises administering to said human an effective HTLV III treatment amount of 3'-azido-3'-deoxythymidine."

Claim 1 of the '538 patent covers "[a] sealed container including a pharmaceutical composition in unit dosage form comprising 5 to 500 mg of 3'-azido-3'-deoxythymidine together with a pharmaceutically acceptable solid carrier."

[4] Claim 1 of the '750 patent covers "[a] method of increasing the number of T-lymphocytes in a human infected with the HTLV III virus comprising administering to said human an effective amount of 3'-azido-3'-deoxythymidine or a pharmaceutically acceptable alkali metal, alkaline earth or ammonium salt thereof."

(or mouse) retroviruses, the Friend leukemia virus and the Harvey sarcoma virus.

At about this time, scientists at the National Institutes of Health (NIH), led by Samuel Broder, were looking for effective AIDS therapies as well. Unlike Burroughs Wellcome, Broder and his colleagues used live HIV, and were able to develop a test that could demonstrate a compound's effectiveness against HIV in humans using a unique line of T-cell clones (the ATH8 cell line). The NIH scientists began to seek compounds from private pharmaceutical companies for screening in their cell line. After Burroughs Wellcome contacted Broder in the fall of 1984, he agreed to accept compounds from Burroughs Wellcome under code for testing against live HIV.

Burroughs Wellcome's Rideout selected AZT and a number of other compounds for testing in the murine screens on October 29, 1984. The tests, performed at Burroughs Wellcome facilities by St. Clair, showed that AZT had significant activity against both murine retroviruses at low concentrations. In light of these positive results, the Burroughs Wellcome inventors met on December 5, 1984, to discuss patenting the use of AZT in the treatment of AIDS. Burroughs Wellcome's patent committee thereafter recommended that the company prepare a patent application for future filing. By February 6, 1985, the company had prepared a draft application for filing in the United Kingdom. The draft disclosed using AZT to treat patients infected with HIV, and set out various pharmaceutical formulations of the compound in an effective dosage range to treat HIV infection.

Two days earlier, on February 4, 1985, Burroughs Wellcome had sent a sample of AZT, identified only as Compound S, to Broder at NIH. In an accompanying letter, Lehrman told Broder of the results of the murine retrovirus tests and asked that he screen the compound for activity against HIV in the ATH8 cell line. Another NIH scientist, Hiroaka Mitsuya, performed the test in

mid-February 1985, and found that Compound S was active against HIV. Broder informed Lehrman of the results by telephone on February 20, 1985. Burroughs Wellcome filed its patent application in the United Kingdom on March 16, 1985.

After Burroughs Wellcome learned that AZT was active against HIV, it began the process of obtaining Food and Drug Administration (FDA) approval for AZT as an AIDS therapy. As a part of the clinical trials leading to FDA approval, Broder and another NIH scientist, Robert Yarchoan, conducted a Phase I human patient study which showed that treatment with AZT could result in an increase in the patient's T-cell count. Broder reported this result to Lehrman on July 23, 1985. In 1987, the FDA approved AZT for marketing by Burroughs Wellcome; Burroughs Wellcome markets the drug for treatment of HIV infection under the trademark Retrovir.

On March 19, 1991, Barr Laboratories, Inc. (Barr) sought FDA approval to manufacture and market a generic version of AZT by filing an Abbreviated New Drug Application (ANDA) pursuant to 21 U.S.C. § 355(j) (1988). As part of the process, Barr certified to the FDA that Burroughs Wellcome's patents were invalid or were not infringed by the product described in its ANDA. After Barr informed Burroughs Wellcome of its action, Burroughs Wellcome commenced this case for patent infringement against Barr on May 14, 1991, alleging technical infringement of its patents under 35 U.S.C. § 271(e)(2)(A) (1988).

Barr filed a counterclaim under 35 U.S.C. § 256 (1988) seeking correction of the patents to list Broder and Mitsuya as coinventors. Barr admitted that its AZT product would infringe the patents, but contended that it did not because Barr had obtained a license to manufacture and sell AZT from the government, which should be deemed the owner of the interest of coinventors Broder and Mitsuya in the AZT patents. Burroughs Wellcome

denied that Broder and Mitsuya were coinventors and also responded that the assertion of any rights of Broder, Mitsuya, or the government in the patents was barred by laches, estoppel, and waiver.

Thereafter, Novopharm, Ltd. filed an ANDA of its own, seeking approval to manufacture and market its generic version of AZT. Burroughs Wellcome filed infringement suits against Novopharm, Ltd. and its American subsidiary Novopharm, Inc., which were consolidated with the suit against Barr.[5] Like Barr, Novopharm, Ltd. admitted that its AZT product would infringe the claims of the six patents, but for the failure of Burroughs Wellcome to name the NIH scientists as coinventors of the subject matter of the patents. Although Novopharm, Inc., agreed to be bound by any injunction issued against its parent, it argued that it had not infringed the patents because it had not filed an ANDA and had no AZT product of its own.[6] Novopharm contended that Broder and Mitsuya should have been named as inventors on five of the patents, and contended that Broder and Yarchoan were coinventors of the '750 patent. It maintained that the patents were invalid because of the alleged nonjoinder, and because Burroughs Wellcome had omitted the coinventors with deceptive intent, the patents were unenforceable for inequitable conduct.

After more than three weeks of trial, while Burroughs Wellcome was still in the process of presenting its case,

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[5] Novopharm, Inc. and Novopharm, Ltd. are jointly represented by counsel and make many of the same arguments on appeal. Except where it is more appropriate to refer to them individually, we will refer to them together as Novopharm.

[6] Burroughs Wellcome alleges that Novopharm, Inc. is liable for the infringement by Novopharm, Ltd. on grounds that it participated in or induced Novopharm, Ltd.'s infringing activities. But Burroughs Wellcome had the burden of proving infringement by Novopharm, Inc. and on the record before us there is simply no evidence to support a conclusion on this factual question. The judgment against Novopharm, Inc. is vacated.

the district court granted Burroughs Wellcome's motion for judgment as a matter of law against all of the defendants, concluding that the Burroughs Wellcome inventors had conceived of the subject matter of the inventions at some time before February 6, 1985, without the assistance of Broder, Mitsuya, or Yarchoan. The court rejected the arguments of Barr and Novopharm that they should be allowed to present evidence that the Burroughs Wellcome inventors had no reasonable belief that the inventions would actually work—that AZT was in fact active against HIV—until they were told the results of the NIH testing.

The court also rejected Novopharm's argument that the Burroughs Wellcome inventors had not conceived the invention of the '750 patent—the use of AZT to increase a patient's T-cell count—before July 23, 1985, when Broder reported the results of the NIH patient study to Lehrman. The court concluded that the increase in T-cell count was an obvious phenomenon known to the inventors that would result from administration of AZT. And the district court denied Barr's renewed motion for partial summary judgment on Burroughs Wellcome's equitable defenses to its counterclaim for correction of the patents under section 256.

Discussion

The arguments of both Barr and Novopharm are directed to when the inventors conceived the invention. Burroughs Wellcome says it was before they learned the results of the NIH tests; Barr and Novopharm say that confirmation of the inventions' operability, which came from the NIH tests, was an essential part of the inventive process. If Burroughs Wellcome is right, then the patents name the proper inventors, they are not invalid, and the appellants are liable for infringement. If Barr and Novopharm are correct, then Broder, Mitsuya, and Yarchoan should have been named as joint inventors and the resolution of Burroughs Wellcome's infringement suits is premature.

The district court's grant of judgment as a matter of law under Rule 50(a) is subject to de novo review. *Read Corp. v. Portec, Inc.*, 970 F.2d 816, 821, 23 USPQ2d 1426, 1431 (Fed.Cir.1992). We must apply the same standard as did that court, examining the record in the light most favorable to the nonmovant and drawing inferences in that party's favor. We may affirm only if the judgment entered was the only one possible under the controlling law. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 250, 106 S.Ct. 2505, 2511, 91 L.Ed.2d 202 (1986).

A joint invention is the product of a collaboration between two or more persons working together to solve the problem addressed. 35 U.S.C. § 116 (1988); *Kimberly-Clark Corp. v. Procter & Gamble Distrib. Co.*, 973 F.2d 911, 917, 23 USPQ2d 1921, 1926 (Fed.Cir.1992). People may be joint inventors even though they do not physically work on the invention together or at the same time, and even though each does not make the same type or amount of contribution. 35 U.S.C. § 116. The statute does not set forth the minimum quality or quantity of contribution required for joint inventorship.

Conception is the touchstone of inventorship, the completion of the mental part of invention. *Sewall v. Walters*, 21 F.3d 411, 415, 30 USPQ2d 1356, 1359 (Fed.Cir. 1994). It is "the formation in the mind of the inventor, of a definite and permanent idea of the complete and operative invention, as it is hereafter to be applied in practice." *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1376, 231 USPQ 81, 87 (Fed.Cir.1986) (citation omitted). Conception is complete only when the idea is so clearly defined in the inventor's mind that only ordinary skill would be necessary to reduce the invention to practice, without extensive research or experimentation. *Sewall*, 21 F.3d at 415, 30 USPQ2d at 1359; *see also Coleman v. Dines*, 754 F.2d 353, 359, 224 USPQ 857, 862 (Fed.Cir.1985) (conception must include every feature of claimed invention). Because it is a mental act,

courts require corroborating evidence of a contemporaneous disclosure that would enable one skilled in the art to make the invention. *Coleman v. Dines*, 754 F.2d at 359, 224 USPQ at 862.

Thus, the test for conception is whether the inventor had an idea that was definite and permanent enough that one skilled in the art could understand the invention; the inventor must prove his conception by corroborating evidence, preferably by showing a contemporaneous disclosure. An idea is definite and permanent when the inventor has a specific, settled idea, a particular solution to the problem at hand, not just a general goal or research plan he hopes to pursue. *See Fiers v. Revel*, 984 F.2d 1164, 1169, 25 USPQ2d 1601, 1605 (Fed.Cir. 1993); *Amgen, Inc. v. Chugai Pharmaceutical Co.*, 927 F.2d 1200, 1206, 18 USPQ2d 1016, 1021 (Fed.Cir. 1991) (no conception of chemical compound based solely on its biological activity). The conception analysis necessarily turns on the inventor's ability to describe his invention with particularity. Until he can do so, he cannot prove possession of the complete mental picture of the invention. These rules ensure that patent rights attach only when an idea is so far developed that the inventor can point to a definite, particular invention.

But an inventor need not know that his invention will work for conception to be complete. *Applegate v. Scherer*, 332 F.2d 571, 573, 141 USPQ 796, 799 (CCPA 1964). He need only show that he had the idea; the discovery that an invention actually works is part of its reduction to practice. *Id.; see also Oka v. Youssefyeh*, 849 F.2d 581, 584 n. 1, 7 USPQ2d 1169, 1171 n. 1 (Fed.Cir.1988).

Barr and Novopharm suggest that the inventor's definite and permanent idea must include a reasonable expectation that the invention will work for its intended purpose. They argue that this expectation is of paramount importance when the invention deals with uncer-

tain or experimental disciplines, where the inventor cannot reasonably believe an idea will be operable until some result supports that conclusion. Without some experimental confirmation, they suggest, the inventor has only a hope or an expectation, and has not yet conceived the invention in sufficiently definite and permanent form. But this is not the law. An inventor's belief that his invention will work or his reasons for choosing a particular approach are irrelevant to conception. *MacMillan v. Moffett*, 432 F.2d 1237, 1239, 167 USPQ 550, 552 (CCPA 1970).

To support their reasonable expectation rule, Barr and Novopharm point to a line of cases starting with *Smith v. Bousquet*, 111 F.2d 157, 45 USPQ 347 (CCPA 1940), establishing the so-called doctrine of simultaneous conception and reduction to practice.[7] *Smith* was an interference priority contest between alleged inventors of the use of two known compounds as insecticides. Both parties asserted priority based on testing of the compounds against selected insect species. Noting the unpredictability of the experimental sciences of chemistry and biology, in particular the uncertain relationship between chemical structure and biological activity, *Smith* declined to find conception until the invention had been reduced to practice by the filing of the first patent application. *Id.* at 162, 45 USPQ at 352. Barr and Novopharm read this and subsequent cases to establish, or at least support, their rule that conception of an invention in an unpredictable field occurs only when the inventor has reasonable grounds to believe the invention will work.

But these cases do not stand for the proposition that an inventor can never conceive an invention in an unpre-

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[7] Barr and Novopharm also point to dictum in *Biel v. Chessin*, 347 F.2d 898, 146 USPQ 293 (CCPA 1965), suggesting that conception of a method of treating the human body requires a reasonable understanding that the method will work for its intended purpose. No court has applied this dictum as controlling, and we decline to do so here.

dictable or experimental field until reduction to practice. In rejecting the asserted evidence of conception, *Smith* said as to one of the compounds:

> it is apparent from the record that neither [party] had in mind at the time the suggestions were originally made, nor at any time thereafter, until successful tests, if any, were made, what insects, if any, it might be effective against, or how it might be applied to produce the desired results. Accordingly, neither party had a definite idea of the "complete and operative invention" here involved prior to a successful reduction—actual or constructive—of it to practice.

Id. Thus, in awarding priority to Smith based on his constructive reduction to practice, the court relied not on the inherent unpredictability of the science, but on the absence of any evidence to corroborate an earlier conception for either of the parties.

It is undoubtedly true that "[i]n some instances, an inventor is unable to establish a conception until he has reduced the invention to practice through a successful experiment." *Amgen*, 927 F.2d at 1206, 18 USPQ2d at 1021; *Alpert v. Slatin*, 305 F.2d 891, 894, 134 USPQ 296, 299 (CCPA 1962) (no conception "where results at each step do not follow as anticipated, but are achieved empirically by what amounts to trial and error"). But in such cases, it is not merely because the field is unpredictable; the alleged conception fails because, as in *Smith*, it is incomplete. Then the event of reduction to practice in effect provides the only evidence to corroborate conception of the invention.

Under these circumstances, the reduction to practice can be the most definitive corroboration of conception, for where the idea is in constant flux, it is not definite and permanent. A conception is not complete if the subsequent course of experimentation, especially experimental failures, reveals uncertainty that so undermines

the specificity of the inventor's idea that it is not yet a definite and permanent reflection of the complete invention as it will be used in practice. *See Amgen*, 927 F.2d at 1207, 18 USPQ2d at 1021 (no conception until reduction to practice where others tried and failed to clone gene using suggested strategy); *Rey-Bellet v. Engelhardt*, 493 F.2d 1380, 1387, 181 USPQ 453, 457-58 (CCPA 1974) (focusing on nature of subsequent research as indicator that inventors encountered no perplexing intricate difficulties). It is this factual uncertainty, not the general uncertainty surrounding experimental sciences, that bears on the problem of conception.

Barr and Novopharm argue for a broader reading of *Amgen* and *Fiers* in support of their reasonable expectation rule. Both of these cases involve conception of a DNA encoding a human protein—a chemical compound. Conception of a chemical substance includes knowledge of both the specific chemical structure of the compound and an operative method of making it. *Fiers*, 984 F.2d at 1169, 25 USPQ2d at 1604; *Amgen*, 927 F.2d at 1206, 18 USPQ2d at 1021; *Oka*, 849 F.2d at 583, 7 USPQ2d at 1171. The alleged inventors in *Fiers* and *Amgen* claimed conception of their respective inventions before they knew relevant chemical structure—the nucleotide sequence—so the courts found no conception until experimentation finally revealed that structure. Here, though, Burroughs Wellcome's inventions use a compound of known structure; the method of making the compound is also well known.

We emphasize that we do not hold that a person is precluded from being a joint inventor simply because his contribution to a collaborative effort is experimental. Instead, the qualitative contribution of each collaborator is the key—each inventor must contribute to the joint arrival at a definite and permanent idea of the invention as it will be used in practice.

Nor do we suggest that a bare idea is all that conception requires. The idea must be definite and permanent in the sense that it involves a specific approach to the particular problem at hand. It must also be sufficiently precise that a skilled artisan could carry out the invention without undue experimentation. And, of course, the alleged conception must be supported by corroborating evidence. On the facts before us, it is apparent that the district court correctly ruled against Barr and Novopharm as to five of the patents, but that the court's judgment as to the sixth, the '750 patent, was premature.

The '232, '838, '130, '208, and '538 patents encompass compositions and methods of using AZT to treat AIDS. The Burroughs Wellcome inventors claim conception of these inventions prior to the NIH experiments, based on the draft British patent application. That document is not itself a conception, for conception occurs in the inventors' minds, not on paper. The draft simply corroborates the claim that they had formulated a definite and permanent idea of the inventions by the time it was prepared.

The Burroughs Wellcome inventors set out with the general goal of finding a method to treat AIDS, but by the time Broder confirmed that AZT was active against HIV, they had more than a general hope or expectation. They had thought of the particular antiviral agent with which they intended to address the problem, and had formulated the idea of the inventions to the point that they could express it clearly in the form of a draft patent application, which Barr and Novopharm concede would teach one skilled in the art to practice the inventions. The draft expressly discloses the intended use of AZT to treat AIDS. It sets out the compound's structure, which, along with at least one method of preparation, was already well known. The draft also discloses in detail both how to prepare a pharmaceutical formulation

of AZT and how to use it to treat a patient infected with HIV. The listed dosages, dose forms, and routes of administration conform to those eventually approved by the FDA. The draft shows that the idea was clearly defined in the inventors' minds; all that remained was to reduce it to practice—to confirm its operability and bring it to market. *See Haskell v. Colebourne*, 671 F.2d 1362, 1365-66, 213 USPQ 192, 194 (CCPA 1982) (enabling draft patent application sufficient to corroborate conception).

An examination of the events that followed the preparation of Burroughs Wellcome's draft confirms the soundness of the conception. Broder and Mitsuya received from Burroughs Wellcome a group of compounds, known to Broder and Mitsuya only by code names, selected for testing by the Burroughs Wellcome inventors. They then tested those compounds for activity against HIV in their patented cell line. The test results revealed for the first time that one of the compounds, later revealed to be AZT, was exceptionally active against the virus.

Here, though, the testing was brief, simply confirming the operability of what the draft application disclosed. True, the science surrounding HIV and AIDS was unpredictable and highly experimental at the time the Burroughs Wellcome scientists made the inventions. But what matters for conception is whether the inventors had a definite and permanent idea of the operative inventions. In this case, no prolonged period of extensive research, experiments, and modification followed the alleged conception. By all accounts, what followed was simply the normal course of clinical trials that mark the path of any drug to the marketplace.

That is not to say, however, that the NIH scientists merely acted as a "pair of hands" for the Burroughs Wellcome inventors. Broder and Mitsuya exercised considerable skill in conducting the tests, using their patented

cell line to model the responses of human cells infected with HIV. Lehrman did suggest initial concentrations to Broder, but she hardly controlled the conduct of the testing, which necessarily involved interpretation of results for which Broder and Mitsuya, and very few others, were uniquely qualified. But because the testing confirmed the operability of the inventions, it showed that the Burroughs Wellcome inventors had a definite and permanent idea of the inventions. It was part of the reduction to practice and inured to the benefit of Burroughs Wellcome.

Barr and Novopharm allege error in the district court's refusal to hear their evidence of the poor predictive value of the murine retrovirus screens for activity against HIV. Regardless of the predictive value of the murine tests, however, the record shows that soon after those tests, the inventors determined, for whatever reason, to use AZT as a treatment for AIDS, and they prepared a draft patent application that specifically set out the inventions, including an enabling disclosure. Obviously, enablement and conception are distinct issues, and one need not necessarily meet the enablement standard of 35 U.S.C. § 112 to prove conception. *See Fiers*, 984 F.2d at 1169, 25 USPQ2d at 1605. But the enabling disclosure does suffice in this case to confirm that the inventors had concluded the mental part of the inventive process—that they had arrived at the final, definite idea of their inventions, leaving only the task of reduction to practice to bring the inventions to fruition.

The question is not whether Burroughs Wellcome reasonably believed that the inventions would work for their intended purpose, the focus of the evidence offered by Barr and Novopharm, but whether the inventors had formed the idea of their use for that purpose in sufficiently final form that only the exercise of ordinary skill remained to reduce it to practice. *See MacMillan v. Moffett*, 432 F.2d at 1239, 167 USPQ at 552 (Inventor's "reasons or

lack of reasons for including U-5008 are not relevant to the question of conception. The important thing is that he did think in definite terms of the method claimed."). Whether or not Burroughs Wellcome believed the inventions would in fact work based on the mouse screens is irrelevant.

We do not know precisely when the inventors conceived their inventions, but the record shows that they had done so by the time they prepared the draft patent application that thoroughly and particularly set out the inventions as they would later be used. The district court correctly ruled that on this record, the NIH scientists were not joint inventors of these inventions.

The '750 patent is another question. It claims "[a] method of increasing the number of T-lymphocytes in a human infected with the [HIV] virus comprising administering to said human an effective amount of" AZT. Novopharm argues that there is no evidence, under any test of inventorship, that the Burroughs Wellcome inventors conceived of this invention until after the Phase I patient study conducted by Broder and Yarchoan revealed that AZT could lead to increased levels of T-cells in AIDS patients.

Novopharm is right that the record is devoid of any statement that the inventors thought AZT could raise a patient's T-cell levels, but evidence need not always expressly show possession of the invention to corroborate conception. The district court held that the record supported conception as a matter of law, concluding that "an increase in T-lymphocyte count was an 'obvious,' natural phenomenon known to the [Burroughs Wellcome] inventors that would result from the inhibition of a retrovirus." *Burroughs Wellcome Co. v. Barr Lab., Inc.*, 828 F.Supp. at 1213. Burroughs Wellcome argues that this conclusion was proper because increased T-cell count is simply an obvious property or use of the greater discovery at issue here, the treatment of HIV infection with AZT. Because

an increase in T-lymphocytes follows inevitably from treatment of AIDS patients with AZT, Burroughs Wellcome says, Broder and Yarchoan merely observed that the method invented by the Burroughs Wellcome inventors had qualities that the inventors failed to perceive. Burroughs Wellcome says this is not an inventive contribution to the claims of any of the AZT patents.

But even though all six patents arise from the same parent application and are subject to terminal disclaimers to avoid rejection for obviousness-type double patenting, each patent claims a different invention.[8] *See In re Longi*, 759 F.2d 887, 892, 225 USPQ 645, 648 (Fed.Cir.1985) (inventor can get only one patent for any single invention). It is true that the Patent Office determined that the method of the '750 patent would have been obvious to those skilled in the art in light of the inventions claimed in the other patents. That is, however, irrelevant to the question whether the Burroughs Wellcome inventors had conceived of the invention before they learned the results of the Phase I trials. For conception, we look not to whether one skilled in the art could have thought of the invention, but whether the alleged inventors actually had in their minds the required definite and permanent idea. *Cf. Bosies v. Benedict*, 27 F.3d 539, 543, 30 USPQ2d 1862, 1865 (Fed.Cir.1994) (testimony of noninventor as to noninventor's understanding of inventor's written formula insufficient to prove conception). The record does not now support resolution of this question as a matter of law.

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[8] We must assume for the purposes of this case that the '750 patent is drawn to an invention different from each of the other five patents. The parties do not ask us to decide whether claims drawn to an effect or mechanism of action of AZT—its ability to raise T-cell count—reach the same invention as (that is, are inherent in) claims drawn to use of the drug to treat HIV infection or AIDS, and we express no opinion on that. The dissent therefore goes beyond the issues presented and the record before us to decide on the basis of what the dissenting judge thinks he knows. That is not the role of an appellate court.

The alleged conception is supported by testimony of Burroughs Wellcome's experts, Burroughs Wellcome's draft Phase I protocol, and the same draft patent application that corroborates conception of the other five inventions. The experts testified that those skilled in the art at the time expected increased immune function to accompany inhibition of HIV. The draft patent application discloses that HIV preferentially destroys T-cells, that AIDS is associated with progressive depletion of T-cells, and that AZT is an effective treatment for HIV infection. Finally, the draft protocol directs the administrators of the Phase I study to monitor patients' T-lymphocyte count. This evidence supports an inference that the Burroughs Wellcome inventors did have the necessary definite and permanent idea, for, given the virus' effect on T-lymphocytes, it seems logical to conclude that stopping the virus might reverse the process of T-cell destruction and restore the body's immune system to a pre-infection state. If this were the only evidence in the record, the court's judgment would be sustained.

But Novopharm offered evidence suggesting that one skilled in the art would not have expected T-cell count to rise. On deposition, Broder testified that prior to the first patient study, "no one knew whether there was such a thing as recovery" of T-cells, based on the NIH's experience with suramin, a drug that entered clinical trials before AZT. Although suramin showed some activity against HIV, inhibition of the retrovirus apparently was not accompanied by increases in T-cell count or restoration of immune functions. Of course, there might be any number of other explanations for the results of the suramin trials; but they might suggest that although those skilled in the art recognized the significance of T-lymphocyte levels in HIV infection and AIDS, they might have expected inhibition of the virus simply to halt the continuing destruction of T-cells, not to increase T-cell count and restore immune function. This could support

an inference that the inventors themselves did not conceive the invention prior to the Phase I study.

Novopharm also contends that Burroughs Wellcome prepared its Phase I protocol in collaboration with Broder and the NIH, possibly from a draft protocol prepared by Broder and Yarchoan pursuant to their study of suramin. These contentions are relevant to the conception inquiry for they tend to undermine the corroborative value of the draft protocol, and might even support joint inventorship based on that draft. *See Coleman v. Dines,* 754 F.2d at 360, 224 USPQ at 863 (document's co-author cannot be considered sole inventor of invention disclosed in document without further proof). Because under Rule 50(a) all inferences must be taken against the moving party, the court's ruling on the '750 patent was inappropriate, and we vacate the judgment to that extent and remand for further proceedings.

Conclusion

Accordingly, the judgment of the United States District Court for the Eastern District of North Carolina is affirmed in part, vacated in part, and remanded.

LOURIE, Circuit Judge, concurring-in-part and dissenting-in-part.

I concur in the majority's decision with respect to the '232, '838, '130, '208, and '538 patents, and join the opinion except for the following:

I do not agree that reduction to practice is corroboration of conception and that the completeness of a conception is affected by subsequent experimental success or failure. These statements confuse the idea of conception with both corroboration and reduction to practice. A conception must be judged as to its completeness in relation to the invention being claimed. It must also be corroborated by evidence independent of the inventor. If subsequent experimentation shows that an invention that was only conceived does not work, that fact does not vitiate the earlier conception. A conception not later reduced to practice may have little significance, but it is important that we not confuse concepts. The conception was still a conception. It is of course possible for an invention to be reduced to practice constructively, *i.e.*, by filing a patent application, rather than actually, by doing the work, in which case the reduction to practice clearly says nothing about the completeness of the conception. Moreover, what matters, in addition to the completeness of a conception, is its date. Corroboration must be of the date of the conception. If the only "corroboration" of the conception is its reduction to practice, corroboration has not occurred concerning the alleged date of conception. Finally on this point, reduction to practice by the inventor is not corroboration because corroboration must be independent of the inventor. Corroboration is not a demonstration that the conceived invention works; it is evidentiary proof that the mental act of invention occurred on a certain date.

I also believe that the issue of joint inventorship is irrelevant here and therefore confusing. If the Burroughs Wellcome inventors had a complete conception, as we

hold, then the NIH scientists were not inventors because the invention had already been made, not because of any shortcomings in their inventive contributions. Thus, there is no need to discuss joint inventorship at all.

I respectfully dissent from the vacating of the court's judgment concerning the '750 patent. I believe that the method of the '750 patent is an inherent, inevitable result of the practice of the other method patents claiming treatment of HIV or AIDS. It seems to be the (or a) mechanism by which the other methods find their use.

Even if it is true that the first vertification or articulation of the increase in the T-cell count occurred in the hands of NIH scientists, this finding inures to the benefit of those who conceived the method of treatment that led to it. The method of the '750 patent is merely a refined definition of the method of the '232 patent, which issued from the original application. The '130 and '208 patents, which also came from applications later filed with the '750 and the composition patents, are also modifications of the original filing. It is common practice for applicants to claim all aspects of their invention and that is what appears to have happened here. An inventor is entitled to the inherent benefits that flow from his or her invention. It is improper to split the inventorship of what is one invention merely because the means by which it was achieved was later verified by scientists acting pursuant to the original conceivers.

The PTO of course issued these patents. During its examination, it determined that the '750 method was obvious over the '232 method. Given a terminal disclaimer, this led to the grant of the patent. More than being obvious, however, the method was inherent in the '232 method and therefore lacking in novelty. *See* 35 U.S.C. § 102 (1988). If, as I believe, the '750 invention does lack novelty over the other patents, its validity may be in question on the ground of double patenting because a terminal disclaimer is not effective to cure a double patenting prob-

lem when the inventions are the same. As long as the inventive entities are also the same, however, it doesn't really matter.

Even assuming that the '750 method is a separate invention, the majority concedes that evidence supports an inference that the Burroughs Wellcome inventors alone conceived the method. The majority goes off the track, however, in relying on Novopharm's offer of evidence that one would not have expected the T-cell count to rise. This is irrelevant if Burroughs Wellcome's inventors had the conception, because the opinion earlier correctly holds that a reasonable expectation of success is not necessary to a conception.

The majority here is inviting the trial court on remand and motion, *see* 35 U.S.C. § 256 (1988), to partially split the inventorship, and presumably also the ownership, of this related collection of patents claiming the physical act of "treating" and the result which the treatment accomplishes. This makes no sense. It amounts to deciding that treating a person in pain with aspirin is one invention and invoking the pain-relieving mechanism by means of that treatment is another. One cannot apparently treat HIV-infected humans with AZT without also increasing the level of T-lymphocytes. The panel is thus inconsistent in upholding the conclusion of the trial court that Burroughs Wellcome's scientists alone conceived the invention of using AZT to treat HIV infections, but then failing to arrive at the same conclusion regarding a patent claiming one of the sequelae of that use.

The real result of the majority's vacating the court's decision on the '750 patent is that, while it may believe that it is affirming the decision on the other patents, it may in practical effect be destroying Burroughs Wellcome's exclusivity for its invention and creating a whole new set of questions. If the trial court joins the NIH inventors, and NIH has licensed the patent to companies intending to sell AZT, will those companies infringe the

'232 and other patents? Is the terminal disclaimer still valid, lacking the consent of one of the assignees? Without a valid terminal disclaimer, is the '750 patent valid? While these questions are not before us, exploring them illustrates the strange consequences of the majority's decision. One the other hand, if the trial court confirms its finding that the T-lymphocyte "invention" was essentially the same invention and inured to the benefit of Burroughs Wellcome, the remand will have been superfluous. Useless and inefficient litigation and burdening of the courts will have resulted.

The trial court's decision should be affirmed across the board because it correctly found that the Burroughs Wellcome inventors solely conceived and are entitled to the inventive benefit of all the claimed inventions.

APPENDIX B

UNITED STATES DISTRICT COURT
E.D. NORTH CAROLINA
NEW BERN DIVISION

Nos. 91-41-CIV-4-H, 92-134-CIV-4-H,
and 92-156-CIV-4-H

BURROUGHS WELLCOME CO.,
Plaintiff,

v.

BARR LABORATORIES, INC.,
Defendant.

BURROUGHS WELLCOME CO.,
Plaintiff,

v.

NOVOPHARM, INC.,
Defendant.

BURROUGHS WELLCOME CO.,
Plaintiff,

v.

NOVOPHARM LTD.,
Defendant.

July 22, 1993

ORDER GRANTING JUDGMENT AS A MATTER OF LAW IN FAVOR OF PLAINTIFF BURROUGHS WELLCOME CO.

MALCOLM J. HOWARD, District Judge.

This matter is before the court on the plaintiff's motion for judgment as a matter of law filed June 30, 1993, and the plaintiff's renewed motion for judgment as a matter of law filed July 5, 1993. Also pending in this matter is the plaintiff's renewed motion for summary judgment filed June 18, 1993.

In the twenty-five months transpiring between the filing of the initial complaint in this consolidated patent infringement action on May 14, 1991, and the commencement of the trial on June 28, 1993, approximately five hundred forty-one pleadings have been filed and dozens of hearings on motions and discovery matters have been conducted by the court. The court has entered eighty-eight written orders and numerous bench rulings. Thus, the court is intimately familiar with the facts of this case and the legal contentions of the parties.

To state that the case has been hotly contested would be an understatement. The parties have amassed learned, experienced and sizable trial teams who have represented their clients zealously and competently.

The administrative complexity of conducting a trial of this magnitude has been enormous for the court and the parties. The sixty-year-old courtroom in New Bern, North Carolina, has been converted into a contemporary "high tech" facility utilizing "real time" court reporting and six computer-integrated video display monitors. It is highly conceivable that the cost of this trial for the parties exceeds $100,000 per day, in addition to the time and expense associated with this court and the jury. As this case enters its fourth week of trial, the parties estimate, somewhat conservatively the court suspects, that the trial will last an additional six to eight weeks.

With this preamble, the court will state briefly a synopsis of the procedural and factual background of the case. A more detailed statement of the procedural and factual background of the case can be found in the court's order dated June 3, 1993, denying plaintiff's motions for partial summary judgment. 828 F.Supp. 1200.

PROCEDURAL BACKGROUND

Plaintiff Burroughs Wellcome Co., ("BW Co."), a research-oriented pharmaceutical company, owns and controls six United States patents covering various methods of using azidothymidine ("AZT") in the treatment of persons infected with the Human Immunodeficiency Virus ("HIV"). BW Co. manufactures and sells AZT under the brand name Retrovir. At issue in this case is the proper naming of inventors on the following six patents owned by BW Co.: 1) U.S. Patent No. 4,724,232, filed September 17, 1985, issued February 9, 1988; 2) U.S. Patent No. 4,828,838, filed October 21, 1987, issued May 9, 1989; 3) U.S. Patent No. 4,833,130, filed October 20, 1987, issued May 23, 1989; 4) U.S. Patent No. 4,837,208, filed October 20, 1987, issued June 6, 1989; 5) U.S. Patent No. 4,818,538, filed October 21, 1987, issued April 4, 1989; and 6) U.S. Patent No. 4,818,750, filed October 20, 1987, issued April 4, 1989. The court will refer to these patents collectively as "the BW Co. patents."

Defendants Barr and Novopharm Ltd. filed Abbreviated New Drug Applications ("ANDA") with the Food and Drug Administration ("FDA") on March 19, 1991, and June 26, 1992, respectively, seeking approval to manufacture and distribute a generic equivalent of Retrovir. Both Barr and Novopharm Ltd. certified to the FDA, pursuant to 21 U.S.C. § 355 and 35 U.S.C. §§ 156, 271(e), that the BW Co. patents were either invalid or not infringed by the filing of their ANDAs. Barr asserted noninfringement for the reason, *inter alia*, that

two scientists employed by the National Institutes of Health ("the NIH"), Dr. Samuel Broder and Dr. Hiroaka Mitsuya, were coinventors of the subject matter claimed in the six BW Co. patents but had not been named as inventors on the patents. Because Barr received a nonexclusive license from the NIH to exploit any patent rights the NIH, as the employer of Dr. Broder and Dr. Mitsuya, might have in the BW Co. patents, Barr alleged that its ANDA was not an act of infringement.

Similarly, Novopharm Ltd. asserted that Dr. Broder and Dr. Mitsuya were coinventors of the subject matter claimed in the BW Co. patents, but in support of its contention that the BW Co. patents were invalid. Novopharm Ltd. contended that BW Co. omitted Dr. Broder and Dr. Mitsuya from the BW Co. patents with the intent to deceive the patent office and thereby engaged in inequitable conduct before the patent office. Novopharm Ltd. asserted that this alleged inequitable conduct invalidated the BW Co. patents.

STATEMENT OF FACTS

The BW Co. patents name the following five scientists employed by BW Co. as inventors: Dr. Janet Rideout; Dr. David Barry; Dr. Sandra Lehrman; Ms. Martha St. Clair; and Dr. Phillip Furman (collectively referred to as "the BW Co. inventors"). BW Co. is a world leader in antiviral therapy and experienced in retroviruses. BW Co. has been a leader in all aspects of the development of nucleoside analogs, particularly in their use as effective antiviral compounds.

The BW Co. inventors first began screening compounds for potential use as an AIDS therapy in 1984. In mid-1984, when the scientific community learned that AIDS was caused by a retrovirus, now referred to as HIV, the BW Co. inventors, specifically Ms. St. Clair,

began screening compounds for antiretroviral activity against two murine retroviruses.[1]

On October 29, 1984, Dr. Rideout selected AZT, identified as BW Co. compound 509U81, for testing in the murine screens. Ms. St. Clair tested AZT in the murine screens and reported that AZT showed significant activity against FLV and HaSV at low concentrations. After obtaining these positive results, the BW Co. inventors met on December 5, 1984, to discuss patenting the use of AZT to treat patients infected with HIV. After subsequent meetings held in early January 1985, the BW Co. patent committee recommended that a patent application covering the use of AZT as an AIDS therapy be prepared for future filing.

On February 4, 1985, BW Co. sent a sample of AZT under the code name Compound S to Dr. Broder at the NIH for screening against HIV in human cells. In the letter accompanying the sample, Dr. Lehrman informed Dr. Broder that Compound S had been tested in murine and feline leukemia virus systems and that preliminary data was available showing that HIV replication had been inhibited at certain concentrations. Dr. Lehrman suggested that Dr. Broder screen Compound S at concentrations of 1, 5, 10, and 50 micromolars.

By February 6, 1985, a draft patent application for filing in the United Kingdom was prepared by BW Co. employees and its patent agents and attorneys. This draft application did not name the inventors, but it disclosed how to make various pharmaceutical formulations of AZT in an effective dosage range for the purpose of treating HIV infections in humans. The dosage ranges disclosed in the draft patent application encompassed the recommended dosage ranges approved by the FDA

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[1] The two murine retroviruses used by BW Co. for testing were the Friend leukemia virus ("FLV") and the Harvey sarcoma virus ("HaSV").

in 1987. Based upon the information contained in the draft patent application, three expert witnesses on behalf of BW Co.[2] and one expert witness designated by Barr [3] stated in depositions that the draft patent application teaches one of ordinary skill in the art how to use AZT to treat patients infected with HIV. The draft patent application was reduced to final form and filed in the United Kingdom on March 16, 1985.

Dr. Mitsuya tested Compound S against HIV in human cells in mid-February 1985. His tests demonstrated that Compound S was active against HIV. On February 20, 1985, Dr. Broder phoned Dr. Lehrman to report the results of Dr. Mitsuya's testing.

DISCUSSION

Rule 50(a) of the Federal Rules of Civil Procedure provides that a court may grant judgment as a matter of law during a jury trial when, after a party has been fully heard on the issue, "there is no legally sufficient evidentiary basis for a reasonable jury" to find in favor of that party on that issue. In ruling on a Rule 50(a) motion, the court must consider all of the evidence in the light most favorable to the nonmoving party and determine "whether reasonable triers of fact could draw only one conclusion." *Bond v. Morton Buildings, Inc.*, 815 F.Supp. 944, 945 (S.D.W.Va.1993). To avoid judgment as a matter of law, the nonmoving party must come forward with more than a scintilla of evidence to support the material aspects of his case. *Id.; see also Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 250-52, 106 S.Ct. 2505, 2511-12, 91 L.Ed.2d 202 (1986).

Under Rule 56, summary judgment is proper where "the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any ma-

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[2] Dr. Katz, Dr. White, and Dr. Whitley.

[3] Dr. Levine.

terial fact and that the moving party is entitled to a judgment as a matter of law." The standard for summary judgment under Rule 56 is very similar to the standard for judgment as a matter of law under Rule 50(a).

Inventorship

The above facts are found by the court to be fully supported by the record. The parties and the court agree that the only real dispute in this case is the appropriate legal standard that will apply to these facts. The parties candidly represent to the court that the resolution of the appropriate legal standard is outcome determinative.

In previous rulings, the court has defined conception as the formation in the mind of the inventor of a definite and permanent idea of the complete and operative invention as it is thereafter to be applied in practice. The court refused to adopt the legal standard asserted by the defendants in response to BW Co.'s motion for partial summary judgment that an inventor must have a "reasonable basis" for believing that an invention will work before conception can be complete.

The law of conception as understood by the court is comprised of two elements. The first element relates to the state of mind of the inventor—whether he had a definite and permanent idea of the complete and operative invention. This element is subjective; so long as the idea is sufficiently defined and preserved, the law does not require that the inventor's idea be reasonable, scientifically accurate, or capable of being proved. This legal definition of the first element of conception is the object of the parties' current dispute and permeates the whole of the defendants' case.

The second element asks whether the inventor's idea, as defined and preserved, enables one of ordinary skill in the art to reduce the invention to practice. This ele-

ment is objective. The parties have no quarrel with the court's definition of the second element.

Defendant Barr has argued that the definition of conception requires that the BW Co. inventors must have a definite and permanent idea that AZT would be effective in treating humans suffering from AIDS. Barr contends that it must be permitted to introduce evidence that challenges and undermines the murine screen used by the BW Co. inventors as a basis for their claimed definite and permanent idea that AZT would be effective in treating humans suffering from AIDS. Counsel for Barr has candidly stated that the heart of its case rests on the admissibility of evidence regarding the predictiveness, or lack thereof, of murine screens in forming the idea that AZT would be active against a human retrovirus.

In contrast, BW Co. contends that the phrase "definite and permanent" in the context of conception relates to the inventor's ability to describe and preserve his idea and *not* to the inventor's belief that the idea will actually work.

The court agrees with BW Co.'s contention regarding the definition of conception. The court does not believe that the phrase "definite and permanent idea" requires that the BW Co. inventors *know* that AZT would be effective in treating humans having AIDS. For conception to be complete, the law does not require an idea to be proven to actually work. The defendants candidly admitted that their case depends upon the evidence concerning the reliability or predictiveness of the murine screens used by the BW Co. inventors, which this court determines has no legal relevance.

In light of the candid representations of defendants' counsel that they would be unable to satisfy their burden of proof by clear and convincing evidence under the court's definition of the first element of conception, the

court informed the defendants that it would consider BW Co.'s motions for judgment as a matter of law pursuant to Fed.R.Civ.P. 50(a). With this notification, counsel for the defendants presented written offers of proof and were given additional time to further supplement their offers of proof. The court has very carefully reviewed the defendants' written offers of proof and supplemental offers of proof and afforded them an opportunity to be heard orally.

Having given the defendants the opportunity to be fully heard, the court will set forth its findings and conclusions in light of the legal definition of conception adopted by the court. Reviewing all of the evidence and resolving all inferences in favor of the defendants, the court finds no evidence which would enable the defendants to meet their burden of proof in this case. The pleadings in the case and the evidence presented in three weeks of trial testimony satisfy the court without doubt that no legally sufficient evidentiary basis exists for a reasonable jury to find that the BW Co. inventors did not have a complete conception of the invention independent of the testing performed by Dr. Broder and Dr. Mitsuya. The admissible evidence clearly establishes, and this court finds as a matter of law, that the BW Co. inventors formed a definite and permanent idea of using AZT as a therapy for AIDS without any inventive contribution from Dr. Broder and/or Dr. Mitsuya.

Furthermore, in light of all of the evidence, the court concludes that the BW Co. inventors' idea was sufficiently described to allow one of ordinary skill in the art to practice the invention. The evidence in the record shows that the draft patent application was sufficient to enable one of ordinary skill in the art to practice the invention, that is, to treat a patient infected with HIV with an effective dosage amount of AZT. Thus, the evidence fully satisfies the second element of conception.

In reaching its legal conclusions on the elements of conception, the court has relied upon the holdings in such cases as *Hybritech, Inc. v. Monoclonal Antibodies*, 802 F.2d 1367 (Fed.Cir.1986), *Rey-Bellet v. Engelhardt*, 493 F.2d 1380 (C.C.P.A.1974), *MacMillan v. Moffett*, 432 F.2d 1237 (C.C.P.A.1970), and *Applegate v. Scherer*, 332 F.2d 571 (C.C.P.A.1964). The court notes further that a party who conducts tests wholly at the direction and instruction of another is merely a technician and not a conceiver and acts merely as a "pair of hands." The court finds that this last statement accurately characterizes the role played by Dr. Broder and Dr. Mitsuya. The evidence in the record shows that BW Co. sent Compound S to the NIH with specific instructions and directed the testing performed by Dr. Broder and Dr. Mitsuya.

Accordingly, the court concludes that BW Co. is entitled to judgment as a matter of law. The court finds that the evidence in this case is overwhelming and conclusive that the BW Co. inventors, and only the BW Co. inventors, first conceived of the idea of using AZT as a therapy for treating persons infected with HIV. Their definite and permanent idea was expressed in such documents as the February 6, 1985, draft patent application and the February 4, 1985, letter from Dr. Lehrman to Dr. Broder. In addition, the court has heard and considered the testimony of the inventors regarding their formation of the idea that AZT would be an effective AIDS therapy.

The court also finds that the evidence is equally strong in relation to U.S. Patent No. 4,818,750 claiming the use of AZT to increase a patient's T-lymphocyte count. Novopharm Ltd. and Novopharm, Inc., contend that there is no evidence that the BW Co. inventors thought of this use until Dr. Broder and Dr. Yarchoan reported these results following the administration of AZT to a human during clinical trials. However, the court has

heard substantial testimony that an increase in the T-lymphocyte count was an "obvious," natural phenomenon known to the BW Co. inventors that would result from the inhibition of a retrovirus.

Estoppel

Defendant Barr has also renewed its motion for partial summary judgment on the issue of estoppel, laches, and waiver. The court previously denied Barr's motion for partial summary judgment on these issues following oral argument on June 14, 1993. The court found that certain factual determinations precluded the entry of summary judgment.

Barr's primary contention in support of its motion is that the Property Clause of the United States Constitution holds that the government cannot be denied property rights through the assertion of the equitable doctrines of estoppel, laches, and waiver. Under the Property Clause and the cases applying it, government property may be disposed of only as authorized by Congress and government officials without proper authority cannot cause the government to lose its property rights. *See California v. United States*, 457 U.S. 273, 102 S.Ct. 2432, 73 L.Ed.2d 1 (1982); *United States v. California*, 332 U.S. 19, 67 S.Ct. 1658, 91 L.Ed. 1889 (1947). Barr alleges that the government has never authorized the disposal of its patent rights through estoppel, laches, or waiver, and, therefore, these equitable defenses must be dismissed as a matter of law.

The court is not persuaded that the Property Clause is implicated in this action. Although a patent right is a property right, the rights being asserted by Barr in this case have not yet ripened into "property." The patent right being asserted[4] by Barr on behalf of the govern-

[4] The court questions whether the government is, in fact, asserting any rights or taking any action to protect its rights in this

ment in this action is the government's alleged ownership interest in the BW Co. patents.

Barr asserted in its previous motion for partial summary judgment on this issue that ownership rights in a patent inure *automatically* to the government. For the reasons stated below, the court disagrees with Barr's application and interpretation of this statement.

"At the heart of any ownership analysis lies the question of who first invented the subject matter at issue, *because the patent right initially vests in the inventor* who may then, barring any restrictions to the contrary, transfer that right to another, and so forth." *Beech Aircraft Corp. v. EDO Corp.*, 990 F.2d 1237, 1248 (Fed.Cir. 1993) (emphasis added). Only natural persons can be inventors. *Id.* at 1248 n. 2. Because the government is not a natural person, the government cannot be an inventor. Therefore, patent rights cannot vest *automatically* in the government. The government must derive patent rights from an inventor.

In this case, the inventors from whom the government claims an ownership interest are Drs. Broder and Mitsuya. In order for the government to acquire an ownership interest in the BW Co. patents through Drs. Broder and Mitsuya, two conditions must be satisfied. First, Drs. Broder and Mitsuya must be inventors of the BW Co. patents. Second, Drs. Broder and Mitsuya must transfer, by assignment or otherwise, their ownership rights to the government.

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litigation. It is not a party to this proceeding, and it has repeatedly reminded the court that it is not a party to this proceeding. It participated very begrudgingly in discovery, which became the subject of numerous motions to compel culminating in an on-site inspection of the files of the NIH attended by this court. The only action taken by the government to preserve its alleged rights was the negotiation of a licensing agreement with the defendant Barr which obligated Barr to represent the government's interest in this action.

Putting aside the first condition, the court finds that the government is not able to establish the second condition in order to support the contention that the government *has* an ownership interest to protect. Although a formal assignment is not necessary in order for the government to obtain ownership rights in the inventions of its employees, *see* Executive Order 10096; *In re Williams*, 228 U.S.P.Q. 381 (Comm'r Pat.1985), federal regulations provide the proper procedures to be followed when a government employee seeks to establish patent rights. *See* 37 C.F.R. § 100.6(c)(3).

The record is devoid of any evidence showing that Dr. Broder and/or Dr. Mitsuya ever filed or submitted an employee invention report identifying themselves as coinventors of the subject matter of the BW Co. patents. In fact, the court has found no evidence showing that Dr. Broder and/or Dr. Mitsuya ever took *any* action to establish their status as coinventors. Therefore, the court finds no basis for finding that the government has a constitutionally-protected property interest in the BW Co. patents.

Accordingly, the court DENIES Barr's renewed motion for partial summary judgment on the issue of estoppel, latches, and waiver. Whether these equitable doctrines can be applied in this case is a question that cannot be decided as a matter of law. This ruling in no way expresses any opinion as to whether the elements of these doctrines can be satisfied in this case based upon the evidence.

CONCLUSION

For the foregoing reasons, the court hereby GRANTS BW Co.'s motion for judgment as a matter of law pursuant to Fed.R.Civ.P. 50(a)(1). The court finds that the BW Co. inventors had a complete conception, that is, they had a definite and permanent idea of a complete and operative invention as it was thereafter to be applied in practice, independent of any inventive contribution from Dr. Broder and Dr. Mitsuya. Having found that there is

no basis in law for the contention that Dr. Broder and Dr. Mitsuya are coinventors, the court concludes that Novopharm, Inc., and Novopharm Ltd.'s defense of inequitable conduct fail as a matter of law and are hereby DISMISSED.

All other pending motions are hereby DISMISSED.

Pursuant to Fed.R.Civ.P. 50(a), judgment shall forthwith be entered in favor of the plaintiff Burroughs Wellcome Co.

Before we discovered a formula that worked on life-threatening infections, we tested 3,000 that didn't.

Pfizer

Once we uncovered an answer, we didn't stop there. We then tested 27,000 additional formulas to ensure we had the best one. In the end, Pfizer's commitment resulted in a major breakthrough in treating certain infections in people with suppressed immune systems—such as cancer patients on chemotherapy and people with AIDS. With the power of innovation, we can find even more breakthroughs tomorrow. **WE'RE PART OF THE CURE.**

Supreme Court, U.S.
F I L E D
MAY 19 1995

No. 94-1527

IN THE
SUPREME COURT OF THE UNITED STATES
October Term, 1994

Barr Laboratories, Inc.,
Petitioner,

v.

Burroughs Wellcome Co.
Respondent.

ON PETITION FOR WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

RESPONDENT'S BRIEF IN OPPOSITION

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QUESTION PRESENTED

Whether the court below correctly held, based on its *de novo* review of the record, including extensive offers of proof submitted by Petitioner, that Burroughs Wellcome Co. was entitled to judgment as a matter of law on its claim that United States Patents 4,724,232, 4,828,838, 4,833,130, 4,837,208 and 4,818,538 were infringed by Petitioner, were not invalid and named the correct inventors.

IDENTIFICATION OF CORPORATE AFFILIATES PURSUANT TO RULE 29.1

Pursuant to Supreme Court Rule 29.1, Respondent Burroughs Wellcome Co. states that it is a North Carolina corporation and a wholly owned subsidiary of The Wellcome Foundation Ltd., which in turn is a wholly owned subsidiary of Wellcome, p.l.c., which was recently acquired by Glaxo, p.l.c. and which has changed its name to Glaxo Wellcome, p.l.c. All of the subsidiaries of Burroughs Wellcome Co. are wholly owned.

TABLE OF CONTENTS

Page

QUESTION PRESENTED i

IDENTIFICATION OF CORPORATE AFFILIATES PURSUANT TO RULE 29.1 ii

COUNTER-STATEMENT OF THE CASE 2

REASONS FOR DENYING THE WRIT 7

A. Summary of the Argument 7

B. Petitioner's "Reasonable Expectation" Theory is Contrary to Long-Standing Precedent. 8

C. Petitioner's Speculations About Dire Consequences of the Federal Circuit's Decision are Meritless 14

D. Petitioner's "Reasonable Expectation" Theory of Conception Would Lead to Confusion and Would Discourage Cooperative Research . . . 16

E. The Existing Law Imposes a Precise and Rigorous Standard for Conception and Need Not be Changed 19

CONCLUSION 21

TABLE OF AUTHORITIES

Page(s)

CASES

Alpert v. Slatin, 305 F.2d 891,
134 U.S.P.Q. 296 (C.C.P.A. 1962) 10

Amax Fly Ash Corp. v. United States,
514 F.2d 1041, 182 U.S.P.Q. 210 (Ct. Cl. 1975) . . 12

Applegate v. Scherer, 332 F.2d 571,
141 U.S.P.Q. 796 (C.C.P.A. 1964) 9, 12, 13

In re Balzarini, 1991 Pat. App. LEXIS 37
(Bd. Pat. App. & Int. 1991) 17

Brenner v. Manson, 383 U.S. 519 (1966) 19

Cameron & Everett v. Brick, 1871 C.D. 89
(Comm'r Pat. 1871) 8, 9

Diamond Rubber Co. v. Consolidated Rubber Tire Co.,
220 U.S. 428 (1911) 13

Fiers v. Revel, 984 F.2d 1164, 25 U.S.P.Q. 2d 1601
(Fed. Cir. 1993) 9, 16

Great Atlantic & Pacific Tea Co. v.
Supermarket Equipment Corp., 340 U.S. 147 (1950) 19

Hybritech, Inc. v. Monoclonal Antibodies, Inc.,
802 F. 2d 1367, 231 U.S.P.Q. 81 (Fed. Cir. 1986),
cert. denied, 480 U.S. 947 (1987) 5

MacMillan v. Moffett, 432 F.2d 1237,
167 U.S.P.Q. 550 (C.C.P.A. 1970) 10, 13

Mergenthaler v. Scudder, 11 App. D.C. 264,
1897 C.D. 724 (D.C. Cir. 1897) 8

Price v. Symsek, 988 F.2d 1187, 26 U.S.P.Q.2d
1031 (Fed. Cir. 1993) 14

Rey-Bellet v. Engelhardt, 493 F.2d 1380,
181 U.S.P.Q. 453 (C.C.P.A. 1974) 13

CONSTITUTION AND STATUTES

35 U.S.C. § 101 15

35 U.S.C. § 102 15

35 U.S.C. § 102(g) 15, 16

35 U.S.C. § 103 15

OTHER AUTHORITY

Chisum, *Patents*, Vol. 3, § 10.03[1] at 10-27 (1994) . . 16

Collins, *Current Patent Interference Practice*,
§ 4.8 at 86.1 (1992) 16

No. 94-1527

IN THE

SUPREME COURT OF THE UNITED STATES

OCTOBER TERM, 1994

Barr Laboratories, Inc.,
Petitioner,

v.

Burroughs Wellcome Co.
Respondent.

ON PETITION FOR WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

RESPONDENT'S BRIEF IN OPPOSITION

Respondent, Burroughs Wellcome Co. ("BW Co."), respectfully submits that a writ of certiorari to review the judgment of the United States Court of Appeals for the Federal Circuit should not issue, because no question worthy of the exercise of the Court's certiorari jurisdiction is presented.

COUNTER-STATEMENT OF THE CASE

The Petition contains numerous misstatements and omissions with respect to the facts and law, thus necessitating this counter-statement. *See* Supreme Court Rule 15.1. Moreover, Respondent requests that the Court bear in mind that the alleged factual record presented to the District Court and the Federal Circuit by way of Petitioner's offer of proof was extremely one-sided and, Respondent contends, largely inaccurate. However, because this case was decided on a motion under *Fed. R. Civ. P.* 50(a), both lower courts were bound to accept the defendants' factual allegations as true and to draw all inferences in their favor. The Federal Circuit correctly held that the alleged facts upon which Petitioner relies were irrelevant to the issue of inventorship, and that judgment was appropriate as a matter of law based upon facts that are not in dispute.

The principal issue of this case is whether an independently corroborated, fully enabling, written description of the inventions claimed in the patents in dispute was sufficient to establish a legally cognizable conception, irrespective of whether, at the time of such written description, there was a "reasonable expectation" that the inventions would work. The five patents in dispute (the "BW Co. AZT patents") describe and claim pharmaceutical compositions and methods of treating people with Acquired Immune Deficiency Syndrome ("AIDS") and Human Immunodeficiency Virus ("HIV") disease using the drug, 3'-azido-3'-deoxythymidine ("AZT"). Petitioner argues that certain individuals employed by the NIH should have been

named as coinventors on the BW Co. AZT patents, because of the positive results of their blind, *in vitro* screening of AZT.[1] This screening was done at the request of BW Co. pursuant to a confidentiality agreement. A. 7973.[2]

Petitioner cannot dispute, however, that before the NIH employees conducted the blind screening of AZT or ever thought of AZT as a therapy for AIDS or HIV disease, BW Co. had prepared a fully enabling draft patent application describing the claimed inventions as they would thereafter be applied in practice. Pet. App. A, 14a. The draft patent application disclosed the routes of administration, dosage forms and dosing amounts and frequency that would later be approved by the Food and Drug Administration. A. 5321-25, A. 15077-80. As the Federal Circuit stated, Petitioner "concede[s that the draft patent application] would teach one skilled in the art to practice the inventions." Pet. App. A, 13a.

The BW Co. scientists' discovery of the use of AZT as a therapy for AIDS and HIV infection was the result of careful and painstaking research. They designed and implemented a test that allowed them to investigate a large number of candidate drugs. The test employed two different murine (mouse) viruses which, like HIV, were of a special

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[1] An *in vitro* test is one conducted in a laboratory system (e.g., a test tube) as opposed to an *in vivo* test which is performed in a living being. The term "blind screening" refers to the fact that when the NIH scientists screened AZT, it was identified only as "Compound S" -- they admittedly did not know the name or structure of the compound that they were screening.

[2] References to "Pet. App. __" are to the Appendix to the Petition for a Writ of Certiorari. References to "Pet. __" are to the Petition for a Writ of Certiorari. References to "A. __" are to the Record on Appeal.

type, known as a retrovirus. Petitioner does not dispute that the purpose of the murine tests was to identify potential antiviral agents for use in treating people with AIDS and HIV infection. A. 1606, 1655, 1684; A. 789, 792-93; A. 15245-49.

The BW Co. scientists did not select compounds for testing arbitrarily. They focused upon a category of compounds known as "nucleoside analogs." A. 795-96; A. 1618, 1920. Nucleoside analogs are analogs of the building blocks of DNA, and BW Co. had a long history of research with nucleoside analogs for use in treating viral infections, cancer and other diseases.[3] AZT, which is an analog of thymidine, was among the thousands of nucleoside analogs known in 1984. A. 796.

During the Summer and Fall of 1984, BW Co. tested more than one hundred compounds in its murine retrovirus screens. Most of these compounds were nucleoside analogs. A. 1684, 1820, 1823, 1920-21; A. 795-96. AZT was by far the most active compound tested. It was 1,000 times more potent than any antiretroviral compound ever tested at BW Co. and showed no toxicity to the cells used in the culture. A.1695; A. 2623.

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[3] Dr. Broder and his colleagues at the NIH did not focus their attention on nucleos[illegible] analogs until after BW Co. revealed to them that Compound S was [illegible]T. Before his involvement with BW Co., Dr. Broder was directing his attention to a very different type of compound, suramin. Although suramin demonstrated activity against HIV in test tube tests performed in Dr. Broder's laboratory, it turned out to be ineffective as an AIDS therapy, and in fact was extremely toxic. During his seminar at BW Co. in October 1984 (*see* Pet. 5), Dr. Broder tried to get BW Co. involved in his suramin research, but BW Co. was not interested. A. 918.

BW Co. submits that its research leading to the draft patent application is further evidence of its conception of compositions and methods of use of AZT for the treatment of AIDS and HIV disease before any involvement of the NIH. Petitioner does not dispute that BW Co. conducted the above-described research. Instead, Petitioner argues that one could not predict that a drug would be a successful AIDS therapy in humans based exclusively on the results of the murine retrovirus screens.[4] While BW Co. believes that its scientists did have a reasonable basis for believing that they had discovered a useful AIDS therapy, the District Court and the Federal Circuit correctly ruled that whether or not such a basis existed is irrelevant to the question of inventorship. Pet. App. A, 15a-16a.

The Federal Circuit held that conception, the completion of the mental part of invention, is the touchstone of invention. Pet. App. A, 8a. Conception has long been defined as "the formation in the mind of the inventor, of a definite and permanent idea of the complete and operative invention, as it is hereafter to be applied in practice." *Id.*, citing *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F. 2d 1367, 1376, 231 USPQ 81, 87 (Fed. Cir. 1986), *cert. denied*, 480 U.S. 947 (1987).

Holding that the "conception analysis necessarily turns on the inventor's ability to describe his invention with particularity" (Pet. App. A, 9a), the Federal Circuit concluded

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[4] A drug intended for human use must, in addition to having activity against the disease-causing agent, also possess low toxicity and acceptable pharmacological and pharmacokinetic properties. As a result of BW Co.'s previous investigation of AZT as a possible antibacterial agent, the BW Co. scientists were aware of AZT's low toxicity and other advantageous characteristics. A. 15271-76; A. 937-38.

that the BW Co. draft patent application specifically set out the inventions, including an enabling disclosure, which was sufficient in this case

> to confirm that the inventors had concluded the mental part of the inventive process -- that they had arrived at the final, definite idea of their inventions, leaving only the task of reduction to practice to bring the inventions to fruition.

Pet. App. A, 15a.

The court specifically rejected Petitioner's arguments that a reasonable expectation of success that the invention will work is a necessary component of the inventor's definite and permanent idea. Pet. App. A, 9a-10a. The court also rejected the Petitioner's arguments that, in uncertain or experimental disciplines, some experimental confirmation is required before an inventor can have a complete conception. *Id.* Relying on long-standing precedent, the Federal Circuit held that an inventor need not know that the invention will work for conception to be complete, and that the inventor's reasons for choosing a particular approach are irrelevant to conception. *Id.*

For these reasons, the District Court held and the Federal Circuit affirmed that the extent to which the BW Co. murine test results were predictive of the utility of AZT as a therapy for AIDS or HIV disease was irrelevant to the issue of conception and therefore was irrelevant to Petitioner's allegations that the inventorship on the BW Co. AZT patents was incorrect. Both courts were also unpersuaded that Petitioner's allegations concerning the *in vitro* tests performed

at Duke University and at the FDA had any bearing on whether or not the NIH employees were coinventors.[5]

REASONS FOR DENYING THE WRIT

A. Summary of the Argument

Petitioner asks this Court to adopt its poorly defined and illogical "reasonable expectation" test for conception and, in so doing, to overturn more than one hundred years of precedent. This extraordinary request is based on dire and unfounded predictions of the impact of the Federal Circuit's decision and on the suggestion that different standards for conception should apply in uncertain fields of chemistry and biology than in other fields.

In defense of its novel theory, Petitioner confuses concepts of obviousness and utility -- which are requirements for patentability -- with conception, which is the seminal step in the inventive process. Petitioner incorrectly attempts to frame the issue as a choice between a "loose and a rigorous standard of conception." Pet. 18.

The writ should be denied. *First*, the Federal Circuit's decision is consistent with long-standing precedent. There is no conflict among the circuits on this standard, between the Federal Circuit's decision in this case and its decisions in other cases raising inventorship issues or between the rulings in this case and any ruling of this Court. Plenary review by this Court is therefore not warranted. *Second*, Petitioner's speculation that the decision will have a chilling effect on

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[5] Petitioner's unsupported allegations to this Court concerning its license under alleged "inchoate" rights of the NIH in the BW Co. AZT patents, the BW Co. pricing of AZT and Petitioner's alleged pricing plans should it ultimately prevail are completely irrelevant to the issue of inventorship.

research because companies can now simply make "lists" of compounds and thus obtain patent protection is illogical and lacks any historical basis. Federal Circuit precedent requires that an inventor must have conceived of an invention in sufficient detail to enable a person of ordinary skill to practice it. Thus, a complete conception for a pharmaceutical invention may require an inventor to describe such things as effective dosages, routes of administration, how to make the compound and the like. *Third*, if Petitioner's novel theory of conception were adopted, it would create confusion and uncertainty in both inventorship and priority determinations, upsetting decades of patent practice. No court has ever urged such a radical result -- and with good reason. *Fourth*, the issue is not whether a "loose" or "rigorous" standard is applied -- the existing standard of conception, as correctly defined by the Federal Circuit, is precise, demanding and yields predictable results.

B. Petitioner's "Reasonable Expectation" Theory is Contrary to Long-Standing Precedent.

The District Court held that an idea is definite and permanent when an inventor can adequately describe and preserve the idea. Pet. App. B, 31a. The Federal Circuit agreed, holding that "[t]he conception analysis necessarily turns on the inventor's ability to describe his invention with particularity." Pet. App. A, 9a. These holdings are consistent with more than one hundred years of precedent. The case of *Mergenthaler v. Scudder*, 11 App. D.C. 264, 1897 C.D. 724 (D.C. Cir. 1897), which articulated the "definite and permanent" language, relied on *Cameron & Everett v. Brick*, 1871 C.D. 89 (Comm'r Pat. 1871), which held that conception is complete "when [the invention] has assumed such shape in the mind that it can be described and illustrated . . . and when this is evidenced by such description

or illustration as to demonstrate its completeness." 1871 C.D. at 90. The Court of Customs and Patent Appeals, a predecessor of the Federal Circuit, has consistently held that conception turns on the ability of the inventor to describe the invention with sufficient particularity.

> It is sufficient [for conception] if an inventor is able to make a disclosure which would enable a person of ordinary skill in the art to practice the disclosure without extensive research or experimentation.

Applegate v. Scherer, 332 F.2d 571, 572, 141 U.S.P.Q. 796, 798 (C.C.P.A. 1964). The Federal Circuit recently confirmed this principle in *Fiers v. Revel*, 984 F.2d 1164, 1169, 25 U.S.P.Q. 2d 1601, 1605 (Fed. Cir. 1993) ("While one does not need to have carried out one s invention before filing a patent application one does need to be able to describe that invention with particularity.")

This precedent does not distinguish inventions on the basis of the predictability of the technical field within which they reside and, in fact, both of the above-cited cases involved inventions in highly unpredictable fields. The *Applegate* case involved an invention directed to compounds to be added to the Great Lakes for controlling sea lampreys. The *Fiers* case related to the cloning of a human interferon gene in bacteria, using genetic engineering techniques. The key is the ability of the inventor to place the complete invention in the hands of the public via a disclosure that would enable a person of ordinary skill to reduce it to practice. When, as in the present case, that standard is met, it is irrelevant whether the invention is in a predictable or unpredictable field.

Petitioner seeks to find support for its "reasonable expectation" theory from so-called "simultaneous conception and reduction to practice" cases.[6] Pet. 17. In such cases, the invention is the result of trial-and-error research, and the inventor cannot describe how to put the invention into practice until a successful experiment has been performed. *Alpert v. Slatin*, 305 F.2d 891, 894, 134 U.S.P.Q. 296, 299 (C.C.P.A. 1962). The Federal Circuit correctly found these cases to be inapposite, concluding that conception fails not merely because the field is unpredictable, but because prior to the successful experiment, the conception is incomplete, *i.e.*, the inventor cannot yet describe with sufficient specificity how to practice the invention. Pet. App. A, 11a.

Petitioner suggests that the Federal Circuit's opinion is internally inconsistent and "leaves the scientific community without a clear standard as to what constitutes conception in the fields of chemistry and biology." Pet. 11-12. This argument is based on the following language from the Federal Circuit's opinion:

> A conception is not complete if the subsequent course of experimentation, especially experimental failures, reveals uncertainty that so undermines the specificity of the inventor's idea that it is not yet a definite and permanent reflection of the *complete invention as it will be used in practice*.

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[6] The simultaneous conception and reduction to practice doctrine is an evidentiary tool for determining priority of invention, *i.e.*, determining who was the first to arrive at a complete conception. It is inapplicable to the present case, inasmuch as this is an originality and derivation case, not a priority dispute between independent inventors. *See MacMillan v. Moffett*, 432 F.2d 1237, 1240, 167 U.S.P.Q. 550, 553 (C.C.P.A. 1970) (The doctrine of simultaneous conception and reduction to practice does not apply in cases where the issue is originality or derivation.)

Pet. App. A, 11a-12a. (Emphasis added.)[7] Petitioner's characterization of this portion of the Federal Circuit's opinion as "confusing" and internally inconsistent stems from its reading the language out of context. The quoted language appears in the Federal Circuit's discussion of the simultaneous conception and reduction to practice cases. It does not, as Petitioner suggests, mean that a specific and fully enabling conception of an invention ceases to be a conception when there is a subsequent experimental failure. The point is simply that, in trial-and-error research, conceiving of a general goal does not amount to conception when the course of experimentation has not yet revealed to the inventor how the invention will be put into practice. In such a situation, the conception is not yet complete, because the inventor cannot make a disclosure of the invention that would enable its reduction to practice by one of ordinary skill. It is well established that,

> conception has been achieved when 'the inventive idea is crystallized in all of its essential attributes and becomes so clearly defined in the mind of the inventor as to be capable of being converted to reality and reduced to practice by the inventor or by ones skilled in the art.' *Technitrol, Inc. v. United States*, 440 F.2d 1362, 1369-70, 194 Ct.Cl. 596, 609 (1971).

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[7] The Novopharm defendants petitioned the Federal Circuit for rehearing, arguing that this statement in the Court's opinion represented its controlling definition of the law of conception, and that, in view of the alleged "experimental failures" of other entities to whom AZT (denominated as "Compound S") had been sent by BW Co. (Duke University and the U.S. Food and Drug Administration ("FDA")), the District Court's judgment should have been reversed. The Federal Circuit rejected Novopharm's petition without comment. Novopharm has filed a petition for writ of certiorari with this Court based on the same argument.

Amax Fly Ash Corp. v. United States, 514 F.2d 1041, 1047, 182 U.S.P.Q. 210, 215 (Ct. Cl. 1975).

In the present case, there is no dispute that before the NIH even began its blind screening of AZT, the BW Co. scientists had conceived of the use of AZT for treating AIDS and HIV disease in sufficient detail to enable them to describe to a skilled physician how to put the invention into practice.[8] Pet. App. A, 13a-14a. This is all that is required for conception. Since the conception was complete before Drs. Broder and Mitsuya had any involvement with AZT, they cannot be coinventors.

Petitioner is not the first to argue that an inventor must know or have a basis for believing that an invention will work before a conception is complete. The Federal Circuit's predecessor court, the C.C.P.A. has consistently rejected this argument over the past thirty years. In *Applegate v. Scherer*, the C.C.P.A. explicitly rejected the very argument that Petitioner makes here:

> Appellants seem to propose that there cannot be a conception of an invention of the type here involved in the absence of knowledge that the invention will work.

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[8] Petitioner contends that the testing of compounds against HIV in Dr. Broder's ATH8 cell line required special expertise. Pet. 6. Whether or not Dr. Broder's test required special expertise is irrelevant to the completeness of the conception by the BW Co. scientists before the NIH test was commenced. The inventions of the BW Co. AZT patents are directed to the treatment of patients, not the confirmation of activity in a test tube. Regardless of the skill required to perform the test tube procedure, it is not disputed that the BW Co. draft patent application contained sufficient detail to enable a skilled physician to treat a patient with AIDS or HIV disease. Therefore, the conception of the invention *as claimed* was complete before any NIH involvement.

> Such knowledge, necessarily, can rest only on an actual reduction to practice. To adopt this proposition would mean, as a practical matter, that one could never communicate an invention thought by him to another who is to try it out, for, when the tester succeeds, the one who does no more than exercise ordinary skill would be rewarded and the innovator would not be. *Such cannot be the law.*

332 F.2d at 573-74, 141 U.S.P.Q. at 799. (Emphasis added.) Similarly, in *MacMillan v. Moffett*, the C.C.P.A. held that Moffett's reasons or lack of reasons for including a compound in a group to be sent to MacMillan for antiperspirant screening were not relevant to the question of conception. 432 F.2d at 1239, 167 U.S.P.Q. at 552. *Also see, Rey-Bellet v. Engelhardt*, 493 F.2d 1380, 1387, 181 U.S.P.Q. 453, 457-58 (C.C.P.A. 1974) (Conception of an anti-depressant drug held to be complete, notwithstanding the need for extensive animal and human testing, because nothing beyond the exercise of routine skill would have been required to demonstrate the utility of the drug.)

Indeed, an inventor need not even understand the scientific basis for the invention in order to obtain a patent. *Diamond Rubber Co. v. Consolidated Rubber Tire Co.*, 220 U.S. 428, 435-36 (1911) ("It is certainly not necessary that he understand or be able to state the scientific principles underlying his invention, *it is immaterial whether he can stand a successful examination as to the speculative ideas involved.*" (Emphasis in original; citations omitted.)

The adoption of Petitioner's "reasonable expectation" theory of conception would require that long-standing precedent and well-established patent practice be overturned.

Petitioner has fallen far short of justifying such extraordinary action.

Petitioner has also failed to point to any conflict among the circuits, conflict with prior Federal Circuit rulings or conflict between the ruling in this case and any ruling of this Court warranting plenary consideration by this Court.

C. Petitioner's Speculations About Dire Consequences of the Federal Circuit's Decision are Meritless

Petitioner speculates here, as it did before the Federal Circuit, that, unless its "reasonable expectation" theory of conception is adopted, there will be a chilling effect on research. Petitioner contends that the Federal Circuit's decision will allow companies to preempt fields by making long lists of known compounds for testing for a particular utility and to claim that such lists constitute conception of the use of each of the listed compounds. Petitioner's predictions are baseless, and reflect a lack of understanding of the patent system.

First, as is clear from the precedent discussed in the preceding section, a conception cannot be established merely by including a compound on a list. The inventor must have conceived the invention in sufficient detail to enable a person of ordinary skill to reduce it to practice. This conception must be independently corroborated. Pet. App. A, 9a. *Also see Price v. Symsek*, 988 F.2d 1187, 1194-95; 26 U.S.P.Q.2d 1031, 1036-37 (Fed. Cir. 1993). In the pharmaceutical field, a complete conception often requires that the inventor be able to describe the structure of the drug and how to make it along with such details as effective dosages, routes of administration, dosage forms, frequency of dosing and the like.

Moreover, even the establishment of a complete conception does not guarantee the conceiver a patent. The requirements for patentability, including novelty, nonobviousness and utility must be met. 35 U.S.C. §§ 101, 102 and 103. In addition, the rights of one who conceives, but subsequently abandons, suppresses or conceals an invention, will be subordinate to those of a later inventor who perfects and patents the invention. Indeed, one who conceives but does not exercise diligence in reducing the invention to practice will forfeit the patent rights to a later conceiver who is the first to reduce to practice. 35 U.S.C. § 102(g).

Thus, contrary to Petitioner's predictions, one cannot preempt a field simply by making a list. The conception must be sufficiently detailed to enable the reduction of the invention to practice. The conceiver must then act diligently in reducing the invention to practice, and must take steps to place the invention in the hands of the public. Finally, the inventor must establish to the satisfaction of the Patent and Trademark office that the invention is new, useful and nonobvious. Only after meeting all of these standards, will the inventor be rewarded with a patent.

Moreover, the Federal Circuit's decision merely applied the law as it has existed for over one hundred years. The dire consequences predicted by Petitioner simply have not occurred over that time period and, as discussed above, there is no reason that they will occur in the future.

D. Petitioner's "Reasonable Expectation" Theory of Conception Would Lead to Confusion and Would Discourage Cooperative Research

Petitioner's novel proposed test for conception would unnecessarily complicate both priority and inventorship determinations. In patent interferences, priority of inventorship often turns on the question of who was first to conceive. *See, Fiers v. Revel.* In general, priority is awarded to the party who first conceives and reduces the invention to practice. 35 U.S.C. § 102(g). The filing of a patent application which meets the requirements of 35 U.S.C. § 112 has long been recognized as a constructive reduction to practice. Accordingly, the filing date of an enabling patent application conclusively establishes the latest date on which an invention was made. Chisum, *Patents*, Vol. 3, § 10.03[1] at 10-27 (1994). In interference practice, the party with the earliest filing date is designated the "senior party." In general, the senior party will be awarded the patent unless another party can prove a date of invention prior to the senior party's filing date. Collins, *Current Patent Interference Practice*, § 4.8 at 86.1 (1992).

Petitioner's proposed "reasonable expectation" test for conception would substantially change this long-standing approach to the resolution of patent interferences. Under Petitioner's theory, the filing of an enabling patent application would not establish a date of invention unless the applicant could also show that there was a reasonable basis for believing that the invention would work. As the present case demonstrates, it could be expected that in every patent interference in which the junior party could not establish a date of invention prior to the senior party's filing date, the junior party would challenge the "reasonableness" of the senior party's belief that the invention would work. Patent

applications claiming pharmaceutical inventions are often filed before testing in humans or animals has been done; therefore, it could be anticipated that a substantial proportion of such patent applications would be challenged on the basis of the sufficiency of the applicant's data in supporting a reasonable belief that the invention will work.[9]

The uncertainty and confusion created by Petitioner's conception theory would not be limited to patent interference proceedings. Virtually every issued patent in the fields of chemistry, biotechnology and pharmaceuticals would be subject to challenge on the grounds of improper inventorship or invalidity based on prior art or prior invention of another.

Petitioner argues that unless its "reasonable expectation" theory is adopted, the role of the NIH in pharmaceutical research will be adversely affected. Pet. 15. Petitioner's argument is backwards. The NIH has encouraged companies to submit compounds for testing in programs such as the

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[9] It is unclear that the results of Dr. Broder's *in vitro* test would meet Petitioner's "reasonable expectation" standard. *See In re Balzarini*, 1991 Pat. App. LEXIS 37 (Bd. Pat. App. & Int. 1991) (Claim to a method for treating AIDS rejected where only proof of utility was positive activity against the HIV virus in *in vitro* tests similar to those tests used in Dr. Broder's laboratory.) Moreover, Petitioner's test is confusing. During oral argument before the Federal Circuit, Petitioner's counsel was asked whether the "reasonable expectation" test would preclude a genius from establishing a conception based upon insight that might not be considered reasonable by others. Petitioner's counsel responded that a genius would have the reasonable basis for believing that the invention would work. Thus, Petitioner's test is subjective, and the same idea might constitute a conception for one person and not for another. The Patent Office and the courts would have to look into the mind of the putative inventor and perhaps administer an I.Q. test to ascertain whether that person had a reasonable basis for believing that the invention would work.

National Cancer Institute cancer screens. The agency has consistently assured the private sector that patent rights will not be jeopardized by the submission of compounds for testing. For example, the following statement appears in a National Cancer Institute publication, a transcript of the proceedings of the Committee for the Establishment of the Anti-AIDS Screening Program at the National Cancer Institute, Division of Cancer Treatment:

> All this is made possible because of the confidentiality agreement, which we execute with the suppliers. It makes it possible to treat each one of the competing companies in an individual fashion. The key point is when you supply us any compound, you are considered the inventor for all patent purposes.
>
> The conceptional idea starts at the point you donate the compound for screening. (As I said, 98 percent of the compounds we acquire are voluntary contributions from the outside community.) The lead optimization process then is also coupled with this initial fact. So whatever variations we do are simply variants of the initial idea. Again, we do that very carefully by working with the suppliers of the compounds. We do that absolutely ensuring that the patent rights revert back to the original supplier.

Trial Exhibit 1428.

Under Petitioner's theory, patent rights would be severely jeopardized if an inventor were to send a compound to another for testing, and the testing confirmed the activity. The adoption of Petitioner's novel theory of conception would have a chilling effect on cooperative research

activities, particularly those involving government laboratories.

E. The Existing Law Imposes a Precise and Rigorous Standard for Conception and Need Not be Changed

Petitioner argues that the issue is one involving a choice between a "loose" and a "rigorous" standard for conception. In defense of its argument, Petitioner confuses issues of obviousness and utility -- both standards for patentability -- with conception. Conception is the seminal act in the process of invention. The fact that one conceives an invention does not assure one of obtaining a patent. But if a patent does issue, the patent law has traditionally recognized that the person who performed the mental act of conception is the inventor.

Petitioner is correct that the patent statute and applicable Supreme Court precedent establish high standards for patentability. To obtain a patent, the invention must have a practical utility and must not have been obvious over the prior art. However, here there is no question that the inventions claimed in the BW Co. AZT patents meet both the utility and nonobviousness requirements. Petitioner's selective quotations from this Court's opinions in *Brenner v. Manson*, 383 U.S. 519 (1966), and *Great Atlantic & Pacific Tea Co. v. Supermarket Equipment Corp.*, 340 U.S. 147 (1950), are inapposite to the issue of this case. As reflected in the BW Co. draft patent application, the BW Co. scientists conceived of a practical utility of their inventions (the treatment of AIDS and HIV disease), and thus met the standards set forth in *Brenner v. Manson*.

Petitioner unwisely attacks the patent system (Pet. 14-15), when, as a generic drug company, its only source of new

products is the research-oriented pharmaceutical industry. The incentives of the patent system are essential to encouraging investments in the expensive, high-risk research required to bring about new pharmaceutical products.

As discussed above in Section B, the time-honored test for conception which was applied in this case by the District Court and the Federal Circuit cannot seriously be criticized as "loose." To establish a complete conception, an inventor must show, by independently corroborated evidence, possession of all of the details of a complete and operative invention as it will thereafter be applied in practice. The mental conception must be developed to the point that all that is required for its reduction to practice is the exercise of ordinary skill. This standard is rigorous, and undisputed evidence in this case establishes that the BW Co. scientists met that standard before any involvement of the NIH employees.

CONCLUSION

For the foregoing reasons, this case does not warrant plenary review and the Petition for Writ of Certiorari should be denied.

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No. 94-1527

IN THE
Supreme Court of the United States
OCTOBER TERM, 1994

BARR LABORATORIES, INC.,
Petitioner,

v.

BURROUGHS WELLCOME CO.,
Respondents.

On Petition for Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

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PETITIONER'S REPLY MEMORANDUM

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TABLE OF AUTHORITIES

CASES — Page

Alpert v. Slatin, 305 F.2d 891 (C.C.P.A. 1962) 6

Amgen, Inc. v. Chugai Pharmaceutical Co., Ltd., 927 F.2d 1200, 18 U.S.P.Q.2d 1016 (Fed. Cir. 1989), *cert. denied*, 502 U.S. 856 (1991) 4-5, 6

Biel v. Chessin, 347 F.2d 898, 146 U.S.P.Q. 293 (C.C.P.A. 1965) 4, 6

Diamond Rubber Co. v. Consolidated Rubber Tire Co., 220 U.S. 428 (1911) 5

MacMillan v. Moffett, 432 F.2d 1237, 167 U.S.P.Q. 550 (C.C.P.A. 1970) 5, 6

Mergenthaler v. Scudder, 11 App. D.C. 264, 1897 C.D. 724 (D.C. Cir. 1897) 6

Rey-Bellet v. Engelhardt, 493 F.2d 1380, 181 U.S.P.Q. 453 (C.C.P.A. 1974) 5

Smith v. Bosquet, 111 F.2d 157, 45 U.S.P.Q. 347 (C.C.P.A. 1940) 6

STATUTES

35 U.S.C. § 256 2

IN THE

Supreme Court of the United States

OCTOBER TERM, 1994

No. 94-1527

BARR LABORATORIES, INC.,
Petitioner,

v.

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On Petition for Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

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PETITIONER'S REPLY MEMORANDUM

A would-be inventor, Ms. *A*, believes that a particular compound may cure a terrible disease. She thinks that the idea has a one in ten million chance of working (or for that matter, thinks her idea will *not* work). Having a few hours of time on her hands (and living in a first-to-file jurisdiction such as the United Kingdom), she prepares a draft patent application that includes a boilerplate enumeration of all known dosage forms and routes of administration, a dosage frequency of "four or more" per day, and an extraordinarily broad range of "suitable" dosage sizes. Ms. *A* puts the draft application aside and does not then file it.

Dr. *B* is a scientist who is "uniquely qualified" in the field (i.e., not merely the proverbial "pair of hands").

Aware of Dr. *B*'s qualifications, Ms. *A* mentions her idea to Dr. *B* and asks him to see whether it will work. Dr. *B* employs a unique process that he has patented and discovers that the compound in fact will cure the disease. A month after Dr. *B* gives Ms. *A* the happy results of his experiments, Ms. *A* files her patent application, still composed mostly of boilerplate text. Under the decision of the court of appeals in this case, and notwithstanding the patent code's provision for joint inventorship, 35 U.S.C. § 256, Ms. *A* is the *sole* inventor and Dr. *B* has *no* rights in the invention or the resulting patent. Pet. App. 9a, 15a.

Petitioner Barr Laboratories, Inc. (Barr) seeks review of this remarkable proposition. The issue is important to the field of pharmaceutical patents, and the court of appeals' decision allows mere speculation or hope to create patent rights that exclude from coinventorship individuals whose contributions are essential to the conception of the patentable item or process.

Respondents Burroughs Wellcome Co. (BW) does not dispute Barr's characterization of the court of appeals' decision. BW instead contends that the ruling is and should be the law. Respondent's Brief in Opposition (Opposition Brief) at 5-6. BW claims that other, unrelated aspects of the patent code will prevent the mere listing of a compound from constituting conception. *Id.* at 14.

> In the pharmaceutical field, a complete conception often requires that the inventor be able to describe the structure of the drug and how to make it along with such details as effective dosages, routes of administration, dosage forms, frequency of dosing and the like.

Id.

Does this supposed set of limitations protect against premature and unwarranted awards of patent rights? Apparently not. The court of appeals upheld as sufficient

to establish conception a draft patent application setting forth remarkably broad, open-ended ranges.

BW assures us that the pharmaceutical inventor must provide "such details as . . . routes of administration." *Id.* Let us examine the "details" of the route of administration that the court of appeals has said are sufficiently focused to constitute conception:

> The formulations include those suitable for *oral, rectal, nasal, topical (including buccal and sublingual, vaginal or parenteral (including subcutaneous, intramuscular, intravenous and intradermal)* administration.

A. 5323 (emphasis added).[1]

For "details" of dosage forms, the BW application offers the reader brief generic sketches of how to make capsules, tablets, liquids, lozenges, pastilles, mouthwashes, suppositories, snuff-type powder, nasal spray or drops, tampons, gels, creams, foams, and sterile injectable solutions. A. 5323-24.

As for the "details" of effective dosages, the application states that "a suitable effective dose will be in the range *1.0 to 250 mg* per kilogram body weight of recipient per day, preferably in the range of 1 to 100 mg per kilogram body weight per day and most preferably in the range 5 to 40 mg per kilogram body weight per day." A. 5322 (emphasis added).

When frequency of dosing is considered, we are told that "[t]he desired dose is preferably presented as two, three, *four or more* sub-doses" per day, "in unit dosage forms, for example, containing *5 to 500 mg*, preferably 10 to 200 mg and most preferably 20 to 100 mg of active ingredient per unit dosage form." *Id.* (emphasis added). For a patient weighing 150 pounds these boilerplate numbers yield a dosage of between 140 mg and *70,000 mg or more* per day.[2]

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[1] References to "A. ——" are to the Record on Appeal.

[2] 70,000 mg is equal to 154 pounds.

If a requirement for setting forth these kinds of "details" is what protects against unduly free awards of patent rights, BW has done more to make the case for review than anything Barr could say. BW's draft application occupied the entire field of potential "details" by listing virtually every known route of administration and dosage form, a dosage frequency of between two and an infinite number per day, and a "suitable effective" dosage weight ranging from 1 mg all the way up to 250 mg, yet the draft BW application met the test prescribed by the court of appeals.[3]

BW erects and knocks down various other straw issues that are irrelevant to the question presented by the petition. For example, BW claims that Barr would apply a "reasonable expectation" test to all instances of conception of an invention. Opposition Brief at 12. Barr's contention, of course, is that this test applies only in such complex and unpredictable fields as pharmaceutical chemistry and biology—fields where only with suitable experimentation can one have any reliable idea whether a particular compound will work in a particular manner. BW does not even cite, let alone distinguish, one of the principal decisions cited by Barr in support of Barr's position. *Biel v. Chessin*, 347 F.2d 898, 146 U.S.P.Q. 293 (C.C.P.A. 1965), written by no less a patent authority than Judge Giles Rich, teaches that where the invention is "a method of treating the human body . . . , conception thereof is a far different thing than merely thinking of the use of the compound. *There must be some concomitant reasonable understanding or appreciation of the fact that the compound would work* and in what way." *Biel*, 347 F.2d at 902-03, 146 U.S.P.Q. at 296-97 (emphasis added); *see also Amgen, Inc. v. Chugai*

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[3] Additionally, of course, BW's draft patent application was withheld from filing until the NIH tested the drug against the human retrovirus HIV in a human cell system, thereby establishing that AZT actually works. Pet. App. 4a-5a. Only then did BW file its application. *Id.* 5a.

Pharmaceutical Co., Ltd., 927 F.2d 1200, 1207, 18 U.S.P.Q.2d 1016, 1021 (Fed. Cir. 1989) (more than "mere speculation" required) (conception of compound incomplete without ability to define compound), *cert. denied*, 502 U.S. 856 (1991).

BW says that an inventor need not "understand the scientific basis for the invention in order to obtain a patent." Opposition Brief at 13 (citing *Diamond Rubber Co. v. Consolidated Rubber Tire Co.*, 220 U.S. 428, 435-36 (1911)). The issue here, of course, is not whether BW understood how the invention would work but whether one can be an inventor when one has no belief or reason to believe (or even disbelieves) that the idea will work.

BW also offers the unremarkable proposition that where nothing more than routine skill is required to demonstrate the utility of a drug, the individual exercising such skill is not the inventor. *Id.* (citing *Rey-Bellet v. Engelhardt*, 493 F.2d 1380, 1387, 181 U.S.P.Q. 453, 457-58 (C.C.P.A. 1974)). Here, of course, the court of appeals took pains to point out that the contribution of Dr. Broder and his colleagues at NIH was at a level far exceeding routine skill. Pet. App. at 14a-15a. "Broder and Mitsuya, and very few others, were uniquely qualified" to perform the experiments and interpret the results. *Id.*

BW makes much of a decision addressing a proposition not at issue here. Opposition Brief at 13 (citing *MacMillan v. Moffett*, 432 F.2d 1237, 167 U.S.P.Q. 550 (C.C.P.A. 1970)). *MacMillan* rejected the proposition that one must *know* an idea will work in order to be the inventor. *Id.*, 432 F.2d at 1240, 167 U.S.P.Q. at 553. Requiring actual, positive knowledge (as *MacMillan* declined to do) is one thing. Requiring that a would-be inventor have *some* basis for believing an idea will work, or at least requiring that the individual not *disbelieve* that the idea will work, as is the case here, is quite another.

MacMillan is inapposite for another reason. MacMillan was held not to be a coinventor because he "was merely conducting standard tests." *Id.* Here the court of appeals found that testing and evaluation conducted by NIH was anything but "standard." Pet. App. 14a-15a.

None of these straw issues is relevant. The court of appeals found itself at the juncture of two conflicting lines of authority. One line suggests that conception requires only that a would-be inventor state his idea with particularity. *E.g., Mergenthaler v. Scudder,* 11 App. D.C. 264, 1897 C.D. 724 (D.C. Cir. 1897). This line allows little more than speculation to constitute conception, but the issue typically does not arise in fields where existing knowledge itself affords a reasonable expectation whether an invention will work. The second line of decisions recognizes that in complex, unpredictable fields like pharmaceutical chemistry and physiology, "merely thinking of the use of [a] compound" is insufficient to constitute conception. *Biel v. Chessin,* 347 F.2d at 902-03, 146 U.S.P.Q. at 296-97; *accord Smith v. Bosquet,* 111 F.2d 157, 45 U.S.P.Q. 347 (C.C.P.A. 1940).

In attempting to resolve these conflicting lines of authority, the court of appeals has all but wiped out the latter line. In so doing the court has set the threshold for what constitutes conception so low that mere hope or expectation, *Alpert v. Slatin,* 305 F.2d 891, 894 (C.C.P.A. 1962), or mere speculation, *Amgen, Inc. v. Chugai Pharmaceutical Co., Ltd.,* 927 F.2d at 1207, 18 U.S.P.Q.2d at 1021, instead of some reason to believe that an idea will work, henceforth will be sufficient to secure sole inventorship of lucrative pharmaceutical patents. This does violence to the intent of the patent code and should not be permitted.

CONCLUSION

For the reasons set forth in the petition and above, the petition for certiorari should be granted.

Respectfully submitted,

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Nos. 94-1527 and 94-1531

In the Supreme Court of the United States

OCTOBER TERM, 1995

BARR LABORATORIES, PETITIONER

v.

BURROUGHS WELLCOME CO.

NOVOPHARM, INC., AND NOVOPHARM, LTD., PETITIONERS

v.

BURROUGHS WELLCOME CO.

ON PETITIONS FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF FOR THE UNITED STATES AS AMICUS CURIAE

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QUESTIONS PRESENTED

The question presented in No. 94-1527 is whether an inventor must have a reasonable expectation that an invention will work in order to conceive the invention for purposes of federal patent law.

The questions presented in No. 94-1531 are:

1. Whether the factual record before the district court precluded the court from entering judgment as a matter of law in favor of respondent under Rule 50(a) of the Federal Rules of Civil Procedure.

2. Whether, after an invention has been conceived by an inventor, someone who tests the invention with more than ordinary skill thereby becomes a joint inventor.

TABLE OF CONTENTS

	Page
Statement	1
Discussion	9
Conclusion	21

TABLE OF AUTHORITIES

Cases:

Alexander Milburn Co. v. *Davis-Bournonville Co.*, 270 U.S. 390 (1926)	18
Alpert v. *Slatin*, 305 F.2d 891 (C.C.P.A. 1962)	13, 14
Applegate v. *Scherer*, 332 F.2d 571 (C.C.P.A. 1964)	11, 12, 14
Application of Tansel, 253 F.2d 241 (C.C.P.A. 1958)	6, 7
Biel v. *Chessin*, 347 F.2d 898 (C.C.P.A. 1965)	14
Brenner v. *Manson*, 383 U.S. 519 (1966)	15, 16, 18
Coleman v. *Dines*, 754 F.2d 353 (Fed. Cir. 1985)	7, 18
Eli Lilly & Co. v. *Medtronic, Inc.*, 496 U.S. 661 (1990)	5
Field v. *Knowles*, 182 F.2d 593 (C.C.P.A. 1950)	18
Gunter v. *Stream*, 573 F.2d 77 (C.C.P.A. 1978)	7
MacMillan v. *Moffett*, 432 F.2d 1237 (C.C.P.A. 1970)	12, 13, 14
Mergenthaler v. *Scudder*, 11 App. D.C. 264 (D.C. Cir. 1897)	6, 10
Metropolitan Stevedore Co. v. *Rambo*, 115 S. Ct. 2144 (1995)	14
Sewall v. *Walters*, 21 F.3d 411 (Fed. Cir. 1994)	6
Smith v. *Bousquet*, 111 F.2d 157 (C.C.P.A. 1940)	13
The Telephone Cases, 126 U.S. 1 (1888)	10, 11
United States v. *Johnson*, 268 U.S. 220 (1925)	20
Wisniewski v. *United States*, 353 U.S. 901 (1957)	14

Constitution, statutes and rule: Page

U.S. Const. Art. I, § 8, Cl. 8 15
Federal Technology Transfer Act of 1986, 15 U.S.C. 3710a (1988 & Supp. V 1993) 17
21 U.S.C. 355(j) (1988 & Supp. V 1993) 4-5
35 U.S.C. 100(a) 6
35 U.S.C. 101-103 ..... 15, 18
35 U.S.C. 102(g) 6, 18
35 U.S.C. 116 3
35 U.S.C. 262 3
35 U.S.C. 154 15
35 U.S.C. 209(c)(2) 17
35 U.S.C. 256 ..... 3, 5
35 U.S.C. 261-262 15
35 U.S.C. 262 3
35 U.S.C. 271(e)(2) 5
Fed. R. Civ. P. 50(a) 8, 20

Miscellaneous:

AIDS Issues (Part 1): Hearings Before the Subcomm. on Health and the Environment of the House Comm. on Energy and Commerce, 100th Cong., 1st Sess. (1987) 4
3 D. Chisum, *Patents* (1994) 6, 7, 12, 13, 14
S. Rep. No. 283, 99th Cong., 2d Sess. (1986) 17
Steadman's Medical Dictionary (25th ed. 1990) 2
1 *Walker on Patents* (1984) 6

In the Supreme Court of the United States

OCTOBER TERM, 1995

NO. 94-1527

BARR LABORATORIES, PETITIONER

v.

BURROUGHS WELLCOME CO.

NO. 94-1531

NOVOPHARM, INC., AND NOVOPHARM, LTD., PETITIONERS

v.

BURROUGHS WELLCOME CO.

ON PETITIONS FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF FOR THE UNITED STATES AS AMICUS CURIAE

This brief is filed in response to this Court's order inviting the Solicitor General to express the views of the United States.

STATEMENT

Respondent Burroughs Wellcome Co. (Burroughs) holds patents for the use of a pharmaceutical compound called AZT (3'-azido-3'-deoxythymidine) to treat persons infected with the human immuno-deficiency virus (HIV), which causes a disease commonly known as acquired immune deficiency syndrome (AIDS). Burroughs brought suit against petitioner Barr Laboratories, Inc. (Barr) and

petitioners Novopharm, Inc., and Novopharm Ltd. (jointly Novopharm), alleging that those companies had infringed Burroughs' patents. The district court entered judgment for Burroughs (94-1527 Pet. App. 25a-37a), and the court of appeals largely affirmed the district court's decision (*id.* at 1a-23a).

1. In 1984, Burroughs commenced a research program to identify compounds that might be active against HIV, which was known to be a member of the Retroviridae or "retrovirus" family. See *Steadman's Medical Dictionary* 1720 (25th ed. 1990). Burroughs focused its research on a group of compounds known as nucleoside analogs. In October 1984, Burroughs began by screening the compounds against a class of murine (mouse) retroviruses that were thought to be analogous to HIV. Burroughs' testing revealed that administration of low concentrations of AZT produced significant activity against those retroviruses. 94-1527 Pet. App. 3a-4a.

At the time that it was carrying out the murine retrovirus screening program, Burroughs lacked the technical capability to test the compounds using the human retrovirus. However, the National Institutes of Health (NIH), which is a component of the Department of Health and Human Services (HHS), had that capability. Dr. Samuel Broder, a government scientist employed by the NIH, had developed a technique for testing potential AIDS drug treatments against clones of HIV-infected human cells. At Burroughs' request, Dr. Broder undertook to screen compounds supplied by Burroughs against his so-called ATH8 cell line. 94-1527 Pet. App. 4a.

On February 4, 1985, Burroughs supplied Dr. Broder with a sample of AZT, which Burroughs identified only as "Compound S." Two days later, before Dr. Broder had tested the compound, Burroughs prepared a draft British patent application for AZT. The draft patent application

described the use of AZT to treat patients infected with HIV, and it set out various formulations of AZT and associated dosages for administering the treatment. In mid-February 1985, shortly after Burroughs had prepared the draft patent application, one of Dr. Broder's colleagues tested "Compound S" on the ATH8 cell line. He found that the compound was extremely active against HIV. Dr. Broder informed Burroughs of the positive test results on February 20, 1985. 94-1527 Pet. App. 4a.

After receiving those positive results, Burroughs sought approval from the Food and Drug Administration (FDA) to market AZT as an AIDS treatment, and it initiated clinical trials. Burroughs filed British applications for AZT patents in March 1985, and it filed American applications for AZT patents in September 1985. In 1987, Burroughs received FDA approval to market AZT as an AIDS treatment drug. Burroughs eventually received six United States patents for the use of AZT to treat HIV-infected patients. 94-1527 Pet. App. 5a, 26a, 29a.

2. Under United States patent law, if two or more persons jointly make an invention, the patent application must name each of the joint inventors, and if a patent is issued, each inventor (or his assignee) is entitled to practice the invention. 35 U.S.C. 116, 262. See also 35 U.S.C. 256 (describing the procedure for adding omitted inventors and the consequences of a "deceptive" omission). In this case, Burroughs identified five of its own scientists as joint inventors in its AZT patent applications, but it did not name Dr. Broder or any other NIH scientist. See 94-1527 Pet. 7-8.

At the time that Burroughs filed the patent applications, and for a considerable period thereafter, the NIH scientists did not themselves assert a claim of inventorship. See 94-1527 Pet. App. 36a. In 1987, a congressional subcommittee held hearings that raised questions con-

cerning, among other things, the price that Burroughs charged for the AZT treatment. See *AIDS Issues (Part 1): Hearings Before the Subcomm. on Health and the Environment of the House Comm. on Energy and Commerce*, 100th Cong., 1st Sess. 1-52 (1987). Thereafter, the NIH reexamined the role that its scientists had played in testing AZT for Burroughs. Based on that review, the NIH concluded that its scientists had been joint inventors of the patented inventions and should have been named in the Burroughs patent applications. See 94-1527 Pet. 8.

In July 1991, the NIH entered into an AZT licensing agreement with Barr, which manufactures generic drugs. C.A. App. A5368. The agreement stated that the NIH had "inchoate intellectual property rights" in the Burroughs AZT patents. *Id.* at A5386 (§§ 1.02, 2.01). The NIH granted Barr a nonexclusive license to market AZT in the United States for any use approved by the FDA. *Id.* at A5371, A5384, A5387 (§ 3.01, Apps. B & D). In return, Barr agreed to pay the NIH royalties equal to a percentage of Barr's net sales, as well as certain additional sums. *Id.* at A5372-A5373, A5385 (§§ 5.01-5.03 & App. C).

The licensing agreement required Barr to assume responsibility for legal actions "to establish an inventorship/ownership interest on the part of the Government" in the inventions covered by the Burroughs patents. C.A. App. A5388 (§ 15.01). The agreement permitted Barr to count 50% of its "reasonable legal expenses" as a credit against any future royalty obligations to the NIH. *Id.* at A5385, A5388 (§ 15.01 & App. C). However, the agreement did not obligate the federal government itself to participate in the litigation. *Id.* at A5388 (§ 15.01).

3. While the NIH and Barr were negotiating the licensing agreement, Barr took steps that precipitated this patent dispute with Burroughs. In March 1991, Barr applied to the FDA under 21 U.S.C. 355(j) (1988 & Supp. V

1993) for approval to manufacture and sell a generic version of AZT. In June 1992, Novopharm, a generic drug manufacturer that did not obtain a license from the NIH, filed a similar application. The filings of those FDA applications were themselves technical acts of patent infringement under 35 U.S.C. 271(e)(2). See *Eli Lilly & Co.* v. *Medtronic, Inc.*, 496 U.S. 661, 675 (1990).

Burroughs responded by suing Barr and Novopharm for patent infringement in federal district court. See 94-1527 Pet. App. 5a. Barr and Novopharm defended their actions on the ground that the NIH scientists were joint inventors and should have been named in the Burroughs patent applications. *Ibid.* Novopharm additionally contended that the omission of the NIH scientists was the result of "deceptive intent" on the part of Burroughs, rendering the patents invalid and unenforceable. *Id.* at 6a. See 35 U.S.C. 256. The dispute over joint inventorship entailed, among other things, a disagreement over when the inventions were made.

Burroughs contended that its scientists invented the patented uses of AZT no later than February 6, 1985, the date that Burroughs prepared its draft British patent application (see pp. 2-3, *supra*). In contrast, Barr and Novopharm contended that the inventive process was not complete until at least two weeks later, on February 20, 1985, after Dr. Broder and his NIH colleague screened "Compound S" against the ATH8 cell line and reported the favorable test results to Burroughs. If the inventions were made before the NIH scientists screened "Compound S," as Burroughs contended, then the NIH scientists by definition could not be joint inventors. Conversely, if the inventions were not made until after the NIH screening took place, then the role of the NIH scientists might qualify them for joint inventorship. See 94-1527 Pet. App. 7a.

The dispute over when the inventions were made rests on an underlying disagreement over the governing test for "invention" under federal patent law. See 35 U.S.C. 100(a). Generally speaking, the act of invention involves two components, conception and reduction to practice. See 35 U.S.C. 102(g). Conception is the inventor's mental formulation of a complete idea for the product or process. *Sewall* v. *Walters*, 21 F.3d 411, 415 (Fed. Cir. 1994); 3 D. Chisum, *Patents* § 10.04, at 10-48 (1994). Reduction to practice is the process of putting the idea into effect, either by building and testing the invention ("actual" reduction to practice) or by filing an enabling patent application ("constructive" reduction to practice). 3 D. Chisum, *supra*, §§ 10.05-10.06. See also 1 *Walker on Patents* §§ 3.11-3.12 (1984).

In this case, the dispute focused on the element of conception. Although the federal patent statutes refer to conception (see 35 U.S.C. 102(g)), Congress has left the task of defining conception to the courts. The courts have relied on the judicial definition set out in *Mergenthaler* v. *Scudder*, 11 App. D.C. 264 (D.C. Cir. 1897), which states as follows:

> The conception of the invention consists in the complete performance of the mental part of the inventive act. All that remains to be accomplished in order to perfect the act or instrument, belongs to the department of construction, not invention. It is therefore the formation, in the mind of the inventor, *of a definite and permanent idea of the complete and operative invention, as it is thereafter to be applied in practice*, that constitutes an available conception, within the meaning of the patent law.

11 App. D.C. at 276. See, *e.g.*, *Application of Tansel*, 253 F.2d 241, 243 (C.C.P.A. 1958) ("The *Mergenthaler* decision

has been repeatedly cited and approved by this court."); *Gunter* v. *Stream*, 573 F.2d 77, 80 (C.C.P.A. 1978) (following *Mergenthaler*); *Coleman* v. *Dines*, 754 F.2d 353, 359 (Fed. Cir. 1985) (same).

Under the *Mergenthaler* standard, conception is deemed complete when the inventor can describe the invention with sufficient clarity and precision to make an "enabling" disclosure—that is, "a disclosure which would enable a person of ordinary skill in the art" to practice the invention. *Tansel*, 253 F.2d at 243; see also *Coleman*, 754 F.2d at 359; 3 D. Chisum, *supra*, § 10.04[3], at 10-160. In this case, Burroughs contended that the draft British patent application was just such an enabling disclosure and that the preparation of the draft application on February 6, 1985, demonstrated that the Burroughs scientists had conceived the inventions by that date. 94-1527 Pet. App. 7a.

Barr and Novopharm evidently did not dispute that the draft patent application was enabling. See 94-1527 Pet. App. 13a, 29a. However, they contended that in "uncertain" or "experimental" fields, such as biology and pharmacology, conception is not complete until the inventor has a "reasonable expectation" that the invention will work. Under that proposed standard, even if a person has formed an otherwise definite and permanent idea of the invention and has made an enabling disclosure, he cannot be deemed to conceive the invention until he obtains experimental data or other information that would make it reasonable for him to expect the invention to work. In this case, Barr and Novopharm contended that the results of the murine retrovirus screening (see p. 2, *supra*) did not provide a reasonable expectation that AZT would be active against HIV in human cells and that the Burroughs scientists did not have a reasonable expectation until Dr.

Broder informed them of the results of the ATH8 cell line screening. See 95-1527 Pet. 9.

4. In June 1993, the district court commenced a jury trial of the parties' patent infringement and joint inventorship claims. During that trial, Barr and Novopharm sought to introduce evidence bearing on their "reasonable expectation" theory of conception. The district court disallowed the evidence on the ground that, as a matter of patent law, conception does not require the inventor to have a reasonable expectation that the invention will work. After allowing Barr and Novopharm to submit offers of proof on the reasonable expectation issue, the district court entered judgment for Burroughs as a matter of law pursuant to Rule 50(a) of the Federal Rules of Civil Procedure. See 94-1527 Pet. App. 25a-37a.

The Federal Circuit affirmed the judgment with respect to five of the six patents and remanded (for reasons that are not relevant here) with respect to the remaining patent. See 94-1527 Pet. App. 1a-19a. The court of appeals agreed with the district court that the legal test for conception does not include a "reasonable expectation" requirement. *Id.* at 9a-16a. The court held that, as long as the inventor "had an idea that was definite and permanent enough that one skilled in the art could understand the invention," his "belief that his invention will work or his reasons for choosing a particular approach are irrelevant to conception." *Id.* at 9a, 10a.

The Federal Circuit concluded that Burroughs' preparation of the enabling draft British patent application demonstrated that the Burroughs scientists "had formulated a definite and permanent idea of the inventions" before the NIH scientists confirmed that AZT was active against HIV. Hence, the NIH scientists could not be joint inventors. 94-1527 Pet. App. 13a-14a, 15a. The court agreed with Barr and Novopharm that the NIH scientists

had been more than "a pair of hands" in carrying out the ATH8 screening, but reasoned that the screening merely "confirmed the operability of the inventions" and was "part of the reduction to practice" rather than part of the conception. *Id.* at 14a-15a.

DISCUSSION

The legal questions presented in this patent case arise in a dispute involving AZT, which is currently the most widely used medicine for the treatment of AIDS. The outcome of this dispute may affect the price, and consequently the availability, of AZT to AIDS patients. The AIDS epidemic is one of this country's most pressing health problems, and the United States has a strong public health interest in facilitating the availability of AZT to AIDS patients at an affordable price. Nevertheless, the resolution of this case must ultimately turn on the proper construction of federal patent law, which embodies long-standing principles governing inventorship. Indeed, the incentives of the patent system, including the opportunities that system provides for the recoupment of expensive research costs, help to provide hope that more effective means than AZT for treating or preventing AIDS will be forthcoming.

1. The primary issue here is whether an inventor must have a reasonable expectation that an invention will work in order to conceive the invention within the meaning of patent law. In our view, the Federal Circuit's decision is correct. The court's rejection of the "reasonable expectation" standard rests on a sound interpretation of the controlling judicial precedents and does not conflict with any decision of this Court or any other court. The Federal Circuit's decision is also consistent with underlying principles of patent policy. Contrary to Barr's suggestions, it is not likely to impede the development of

future medical treatments for AIDS and other diseases. Accordingly, we do not believe that further review by this Court is warranted.

a. The Federal Circuit did not write its decision on a blank slate. This Court recognized the basic requirements of conception in *The Telephone Cases*, 126 U.S. 1 (1888), which upheld Alexander Graham Bell's right to a patent for the telephone. The Court ruled that Bell had established his conception of the invention when he applied for a patent, even though at that time "he had never actually transmitted telegraphically spoken words so that they could be distinctly heard and understood at the receiving end of his line." *Id.* at 535. The Court rejected the argument that "Bell had not in fact completed his discovery" (*ibid.*), explaining as follows:

> The law does not require that a discoverer or inventor, in order to get a patent for a process, must have succeeded in bringing his art to the highest degree of perfection. It is enough if he describes his method with sufficient clearness and precision to enable those skilled in the matter to understand what the process is, and if he points out some practical way of putting it into operation. This Bell did.

Id. at 536. The District of Columbia Circuit refined that principle in *Mergenthaler*, and for nearly a century, the Federal Circuit and its predecessor, the Court of Customs and Patent Appeals (CCPA), have followed the definition of conception set forth therein. See pp. 6-7, *supra*. That definition does not ask whether the inventor knows, or has reason to believe, that his invention works. Instead, it simply asks whether the inventor has developed "a definite and permanent idea of the complete and operative invention, as it is thereafter to be applied in practice." *Mergenthaler*, 11 App. D.C. at 276 (emphasis omitted).

Under the *Mergenthaler* standard, the test of conception is whether the inventor "is able to make a disclosure which would enable a person of ordinary skill in the art to practice the disclosure without extensive research or experimentation." *Applegate* v. *Scherer*, 332 F.2d 571, 572 (C.C.P.A. 1964). According to the Federal Circuit, Barr and Novopharm conceded that Burroughs' draft British patent application "would teach one skilled in the art to practice the inventions." 94-1527 Pet. App. 13a; see *id.* at 29a. Consequently, Burroughs had satisfied the prevailing test for conception by February 6, 1985, before the NIH scientists screened "Compound S" against the ATH8 cell line.

Contrary to Barr's suggestions (94-1527 Pet. 16-17), neither the Federal Circuit nor the CCPA has ever held that conception is incomplete until the inventor demonstrates a "reasonable expectation" that the invention will work. Indeed, the CCPA specifically rejected proposed tests of conception that would have looked to the inventor's knowledge, or lack of knowledge, about the efficacy of his invention. The CCPA's decision in *Applegate* is illustrative. In that case, a federal agency was conducting a screening program to find compounds that could control sea lampreys. A chemical company contacted the agency to suggest that one of its compounds might be effective. The company sent a sample to the agency, which tested it and found that it was effective. The company and the agency then filed rival patent applications, with each party claiming sole inventorship. See 332 F.2d at 571-572.

The agency argued that the company did not conceive the invention because, at the time that it sent the sample for testing, it did not know whether the compound would work. The CCPA squarely rejected that argument in terms similar to those used by this Court in *The Telephone Cases*, *supra*. The CCPA stated:

> [The agency] seem[s] to propose that there cannot *be* a conception of an invention of the type here involved in the absence of knowledge that the invention will *work*. Such knowledge, necessarily, can rest only on an actual reduction to practice. To adopt this proposition would mean, as a practical matter, that one could never communicate an invention thought up by him to another who is to try it out, for, when the tester succeeds, the one who does no more than exercise ordinary skill would be rewarded and the innovator would not be. Such cannot be the law. A contrary intent is implicit in the statutes and in a multitude of precedents.

332 F.2d at 573-574.

The CCPA's decision in *MacMillan* v. *Moffett*, 432 F.2d 1237 (C.C.P.A. 1970), makes the same point. In *MacMillan*, one company selected antiperspirant compounds for testing by another company. Moffett, a scientist employed by the first company, selected 69 compounds for screening, and the second company's scientists found that one of those compounds was highly effective. The CCPA held that Moffett was the sole inventor, even though he had "no knowledge that [the effective compound] would have new and unexpected properties over the prior art and over the other 68 compounds he selected." *Id.* at 1239. The court held that Moffett's "reasons or lack of reasons for including [the compound] are not relevant to the question of conception. The important thing is that he did think in definite terms of the method claimed." *Ibid.*; see 3 D. Chisum, *supra*, § 10.04[4], at 10-68 to 10-69.[1]

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[1] Strictly speaking, precedents such as *Applegate* and *MacMillan* hold only that an inventor does not need to *know* that his invention works. They do not hold that the inventor does not need a "reasonable expectation" that the invention works. Their reasoning, however, is at

In the lower court proceedings, Barr attempted to support its "reasonable expectation" test by reference to cases in which an invention was simultaneously conceived and reduced to practice. See *Smith* v. *Bousquet*, 111 F.2d 157 (C.C.P.A. 1940); *Alpert* v. *Slatin*, 305 F.2d 891, 894 (C.C.P.A. 1962); see generally 3 D. Chisum, *supra*, § 10.04[5]. According to Barr, those cases demonstrate that conception in speculative fields cannot occur until the inventor acquires a reasonable basis (through experimentation or otherwise) for believing that his invention will work. See 94-1527 Pet. App. 10a. The Federal Circuit carefully reviewed the "simultaneous conception and reduction to practice" cases and concluded that they do not involve an exception to the *Mergenthaler* test, nor do they require proof of "reasonable expectation" as an element of conception in speculative fields of research. See 94-1527 Pet. App. 10a-12a.

As the Federal Circuit explained, the CCPA's opinions in *Smith* and *Alpert* deal with an evidentiary problem under the *Mergenthaler* test—the difficulty of determining when an inventor who is proceeding by "trial and error" (*Alpert*, 305 F.2d at 894) has formed a definite and fixed idea of the ultimate invention. See 94-1527 Pet. App. 10a-11a. In that situation, "the reduction to practice can be the most definitive corroboration of conception, for where the idea is in constant flux, it is not definite and permanent." *Id.* at 11a. In this case, by contrast, the enabling draft British patent application supplied the necessary evidence that Burroughs had arrived at a "definite and permanent" idea of the patented methods of

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odds with a "reasonable expectation" test, for that test rests squarely on the premise that conception is complete as soon as the inventor "think[s] in definite terms of the method claimed." *MacMillan*, 432 F.2d at 1239.

using AZT to treat AIDS. Hence the evidentiary problem involved in cases such as *Smith* was not presented. *Id.* at 16a. See 3 D. Chisum, *supra*, § 10.04[5], at 10-75.[2]

Barr also relied below on a statement in *Biel* v. *Chessin*, 347 F.2d 898 (C.C.P.A. 1965), that when someone invents "a method of treating the human body" with a compound, conception requires "some * * * reasonable understanding or appreciation of the fact that the compound would work." *Id.* at 902-903. The Federal Circuit noted, however, that the quoted language in *Biel* was dictum that had not been treated as controlling in subsequent cases. 94-1527 Pet. App. 10a n.7. That court, which is the CCPA's successor, acted appropriately in declining to give force to that prior dictum. See *Metropolitan Stevedore Co.* v. *Rambo*, 115 S. Ct. 2144, 2149 (1995).

The Federal Circuit's reading of the "simultaneous conception and reduction to practice" cases is consistent with longstanding patent law principles, and its rejection of *Biel*'s never-applied dictum is sound. Prior to the Federal Circuit's ruling in this case, its case law may have created a legitimate question concerning the governing test for conception in "speculative fields," but the court has now dispelled whatever uncertainty existed among its own precedents and has obviated the need for further review. See *Wisniewski* v. *United States*, 353 U.S. 901, 902 (1957) (per curiam) ("It is primarily the task

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[2] The CCPA itself recognized that the concept of "simultaneous conception and reduction to practice" is "rarely applied." *Alpert*, 305 F.2d at 894. It confined that principle to priority disputes involving independent inventors, and it declined to invoke the principle in originality disputes involving collaborative research efforts. See *Applegate*, 332 F.2d at 573; *MacMillan*, 432 F.2d at 1240 ("*Applegate* * * * made it abundantly clear that such a doctrine does not apply in cases where the issue is originality or derivation."); 3 D. Chisum, *supra*, § 10.04[5], at 10-72.

of a Court of Appeals to reconcile its internal difficulties.").

b. The Federal Circuit correctly recognized that Barr's proposed "reasonable expectation" standard is not an established element of existing patent jurisprudence. Barr disagrees with that conclusion, but its principal arguments in this Court rest on policy considerations relating to "patent monopolies." See 94-1527 Pet. 13-14. Barr's policy arguments are not persuasive.

Barr argues that its "reasonable expectation" standard would increase the incidence of joint inventorship and thereby reduce the occurrence of "patent monopolization." See 94-1527 Pet. 16. Barr suggests that when a single inventor or firm holds a patent, it encourages an undesirable "patent monopoly" in which the patentholder is free to charge whatever the market will bear, without having to face competition from other firms selling the same invention. Barr theorizes that when two or more inventors hold a patent, greater competition and lower prices will result, because each inventor has an independent right under 35 U.S.C. 261-262 to market the invention. 94-1527 Pet. 16.

Barr's "patent monopolization" argument has several shortcomings. First, it is in significant tension with the fundamental policies of the patent laws. See U.S. Const., Art. I, § 8, Cl. 8 ("To promote the Progress of Science and useful Arts."). Congress has crafted a patent system that provides a right to exclude, which amounts to a limited legal monopoly as an incentive for the development of socially useful inventions. *Brenner* v. *Manson*, 383 U.S. 519, 534 (1966). Congress has determined the confines of that right, imposing prerequisites (such as utility, novelty, and non-obviousness, 35 U.S.C. 101-103) and restrictions (such as durational limitations, 35 U.S.C. 154). But Barr has pointed to nothing in the patent laws

expressing Congress's intent to promote joint inventorship as a means of limiting that right. At bottom, Barr's argument is an invitation to this Court to assume a legislative role. Barr asks this Court to modify the longstanding test for conception to alter the balance that Congress has struck to spur socially beneficial inventive efforts.[3]

Second, Barr's surmise that a "reasonable expectation" standard would encourage joint inventorship is open to serious question. Barr's argument assumes that a firm that does not yet have a "reasonable expectation" about its invention's efficacy will nonetheless turn the invention over to another firm for testing without first taking steps to protect itself against the potential loss of exclusive patent rights. That assumption is highly dubious. The first firm can generally ask the second firm to yield by contract whatever patent rights the second firm might otherwise acquire through the testing process. If the second firm is unwilling to conduct the testing under those terms, the first firm may be able to find someone else who is willing and able to perform the tests on the same terms. Alternatively, the first firm may be able to develop the necessary testing capabilities "in house," and presumably will do so if the potential economic payout from the invention makes it worthwhile.

Third, even when a "reasonable expectation" requirement would lead to jointly held patent rights in a particu-

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[3] The judicial resolution of patent disputes may affect the economic power of market participants, and courts may take into account the "basic *quid pro quo* contemplated by the Constitution and the Congress for granting a patent monopoly" when they decide patent law issues. *Brenner*, 383 U.S. at 534. But the courts evaluate that factor based on congressional intent and not merely on the basis of sentiments regarding the desirability of the durationally limited rights authorized by the patent law. See, *e.g.*, *id.* at 529, 532-535.

lar case, there is little reason to think that the result will be greater competition and lower prices for the patented invention. Joint inventors ordinarily will have a common interest in maximizing any profits made possible by the patent. As a result, joint inventors will have a strong mutual incentive not to engage in price competition.[4]

In addition to the patent "monopolization" argument, Barr suggests that the Federal Circuit's decision is unsound because it grants patent rights too freely, or at least prematurely, to companies that rely on unsupported speculation rather than research. Barr raises the specter that a firm can "become an inventor by claiming that any number of identified compounds will cure any number of identified diseases" (94-1527 Pet. 15), without believing (or having any basis for believing) that the compounds

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[4] In this case, a federal agency performed the testing at issue. Barr perhaps believes that its "reasonable expectation" standard would broaden the government's joint inventorship rights when it tests products and thereby reduce the prospect of monopoly pricing in those fields where the government conducts research. Such a belief, however, would be very speculative. It is true that government does not share the profit-maximization objectives of a private firm; indeed, federal agencies are prohibited from granting exclusive licenses that would substantially lessen competition or result in undue concentration of economic power. See 35 U.S.C. 209(c)(2). But to the extent that Barr's "reasonable expectation" test would tend to make the government a joint inventor, the government's unwillingness to take part in monopoly pricing would correspondingly increase the incentive for private firms to avoid the joint inventorship "problem" in the first place. The firm might do so either by using non-government testing resources or by entering into pre-testing contractual arrangements that limit the government's patent rights. See Federal Technology Transfer Act of 1986, 15 U.S.C. 3710a (1988 & Supp. V 1993) (authorizing federal laboratories to enter into "cooperative research and development agreements" with private companies and other "collaborating parties" that determine patent and licensing issues at the outset of government involvement); see also S. Rep. No. 283, 99th Cong., 2d Sess. 11 (1986).

actually cure the diseases. Barr implies that firms will be able to acquire new patent rights simply by drawing up lists of compounds and diseases. *Id.* at 18-19.

That scenario is not, in our view, a realistic one. First, even under the *Mergenthaler* standard, conception is not deemed to be complete until the invention has been embodied in an enabling disclosure. See 94-1527 Pet. App. 8a-9a, 13a; *Coleman*, 754 F.2d at 359 ("Conception must be proved by corroborating evidence which shows that the inventor disclosed to others his 'completed thought expressed in such clear terms as to enable those skilled in the art' to make the invention.") (quoting *Field* v. *Knowles*, 183 F.2d 593, 601 (C.C.P.A. 1950)). Second, merely conceiving an invention, without more, does not confer any patent rights whatsoever. The inventor must reduce the invention to practice, either actually or constructively (see p. 6, *supra*), and must do so promptly or risk losing whatever patent rights he might otherwise be entitled to. See 35 U.S.C. 102(g); accord *Alexander Milburn Co.* v. *Davis-Bournonville Co.*, 270 U.S. 390, 400 (1926). Even after conception and reduction to practice are complete, moreover, the inventor must be able to show that his invention satisfies the patent law's substantive requirements for patentability, such as novelty, utility, and non-obviousness. See 35 U.S.C. 101-103; accord *Brenner*, 383 U.S. at 528-536. The traditional test for conception employed by the Federal Circuit in this case does not eliminate those additional legal requirements for obtaining patents, and there is accordingly no reason for companies to respond to this decision, as Barr predicts (94-1527 Pet. Reply Br. 1-2), by spending their time fruitlessly drawing up arbitrary lists of compounds and diseases and putting them into draft patent applications.

On the other side of the coin, adoption of a "reasonable expectation" test would impose a potentially significant

burden on the patent process by complicating the task of proving conception. Under current law, the Patent and Trademark Office and the courts resolve conception disputes by requiring the inventor to present evidence that he had a definite and permanent idea comprising the invention. The inventor can be expected to create documentary evidence on that matter, such as Burroughs' draft patent application or an inventor's work diary, in the ordinary course of developing the invention. There is no reason to believe, however, that inventors routinely develop documentary evidence of their expectations concerning their inventions' effectiveness. As a result, if the approach urged by Barr were to be adopted, the parties and courts would be faced with the task of retrospectively constructing and evaluating a record of the inventor's subjective knowledge and beliefs. That task would encumber administrative proceedings and patent litigation with additional and, in our view, unnecessary uncertainty and expense.

In sum, we see no significant basis for believing that adoption of a "reasonable expectation" test would be desirable as a matter of patent policy. The test would be an administrative encumbrance but would not appear likely to change either the incentives for collaborative development of inventions or the allocation of patent rights among collaborators. There is no reason to believe that the substantial public interest in encouraging development of beneficial products, such as new medicines, would be furthered if the test were to become law.

2. Novopharm's petition (No. 94-1531) presents two additional objections to the decision below. Neither of them warrants review by this Court.

First, Novopharm argues that there was "sufficient evidence in the record" (94-1531 Pet. 8) to foreclose the district court from entering judgment as a matter of law

under Federal Rule of Civil Procedure Rule 50(a). Novopharm does not contest the legal standard for conception employed by the court of appeals, but argues only that "the totality of the evidence" (94-1531 Pet. 12) created an issue of fact for the jury to decide under that standard. *Id.* at 8. The question whether Novopharm's offer of proof (94-1531 Pet. App. 46a-58a) was sufficient to create a jury question under the Federal Circuit's legal standard is a factbound matter that does not warrant further review. See, *e.g.*, *United States* v. *Johnston*, 268 U.S. 220, 227 (1925) ("We do not grant a certiorari to review evidence and discuss specific facts.").

Second, Novopharm argues (94-1531 Pet. 13-14) that once the court of appeals determined that the NIH scientists acted as more than a mere "pair of hands" in screening "Compound S" (94-1531 Pet. App. 18a), the court should have deemed the NIH scientists to be joint inventors as a matter of law. That argument rests on a *non sequitur*. The degree of skill and expertise employed by the NIH scientists might have been relevant to the issue of joint inventorship if the Burroughs scientists had not already conceived the patented inventions when the NIH scientists performed their tests. But once it is recognized that under the findings in this case conception was complete by February 6, 1985, it follows that the skill employed by the NIH scientists thereafter is irrelevant.

CONCLUSION

For the foregoing reasons, the petitions for a writ of certiorari should be denied.

Respectfully submitted.

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No. 94-1527

IN THE
Supreme Court of the United States
OCTOBER TERM, 1995

BARR LABORATORIES, INC.,
Petitioner,

v.

BURROUGHS WELLCOME CO.,
Respondents.

On Petition for Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

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PETITIONER'S SUPPLEMENTAL MEMORANDUM IN REPLY TO BRIEF OF THE UNITED STATES

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RULE 29.6 STATEMENT

Barr Laboratories, Inc. has no parent company. Barr has two subsidiaries, BRL Incorporated and 265 Livingston Street Corp.

TABLE OF CONTENTS

	Page
RULE 29.6 STATEMENT	i
STATEMENT	1
DISCUSSION	2
CONCLUSION	10
APPENDIX	1a

TABLE OF AUTHORITIES

CASES — Page

Alpert v. Slatin, 305 F.2d 891 (C.C.P.A. 1962) 3, 5
Amax Fly Ash Corp. v. United States, 514 F.2d 1041 (Ct. Cl. 1975) 3, 6
Applegate v. Scherer, 332 F.2d 571 (C.C.P.A. 1964) 3
Biel v. Chessin, 347 F.2d 898 (C.C.P.A. 1965) 2, 3
Brenner v. Manson, 383 U.S. 519 (1966) 8
Great Atlantic & Pacific Tea Co. v. Supermarket Equipment Corp., 340 U.S. 147 (1950) 8
MacMillan v. Moffett, 432 F.2d 1237 (C.C.P.A. 1970) 2, 3, 4
Meitzner v. Corte, 410 F.2d 433 (C.C.P.A. 1969) 6, 7
Mueller Brass Co. v. Reading Indus., 352 F. Supp. 1357 (E.D. Pa. 1972), *aff'd*, 487 F.2d 1395 (3d Cir. 1973) 1
New York Times Co. v. United States, 403 U.S. 713 (1971) 8
Smith v. Bosquet, 111 F.2d 157 (C.C.P.A. 1940) 3
The Telephone Cases, 126 U.S. 1 (1888) 6

CONSTITUTION AND STATUTES

35 U.S.C. § 101 9
35 U.S.C. § 116 9

OTHER AUTHORITY

1 D. CHISUM, PATENTS § 2.02[1] (1995) 9
21 C.F.R. § 58.120(a) (1995) 10
21 C.F.R. § 58.185(a)(2) (1995) 10
130 Cong. Rec. H10527 (daily ed. Oct. 1, 1984) 9
S. Ct. R. 10(a) 9
S. Ct. R. 10(c) 2
S. Ct. R. 15.8 1

IN THE

Supreme Court of the United States

OCTOBER TERM, 1995

No. 94-1527

BARR LABORATORIES, INC.,
Petitioner,

v.

BURROUGHS WELLCOME CO.,
Respondents.

On Petition for Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

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PETITIONER'S SUPPLEMENTAL MEMORANDUM IN REPLY TO BRIEF OF THE UNITED STATES

Petitioner Barr Laboratories, Inc. (Barr) files this supplemental memorandum in reply to the brief of the United States as amicus curiae. S. Ct. R. 15.8.

STATEMENT

This case deals with conception in the experimental field of biological science and with joint invention, which has been called "one of the muddiest concepts in the muddy metaphysics of patent law." *Mueller Brass Co. v. Reading Indus.*, 352 F. Supp. 1357, 1372 (E.D. Pa. 1972), *aff'd*, 487 F.2d 1395 (3d Cir. 1973). What constitutes conception of a joint invention in that context is in need of clarification by this Court.

Barr does not contend, as the Solicitor General claims, that in every instance "an inventor must have a reason-

able expectation that an invention will work in order to conceive the invention for purposes of federal patent law." *See* Brief for the United States as Amicus Curiae (U.S. Brief) I. Such a belief is needed only for invention *in an uncertain and experimental field such as biological science.* Petition (No. 94-1527) (Barr Pet.) i. Where an invention is

> a method of treating the human body . . . , conception thereof is a far different thing than merely thinking of the use of the compound. *There must be some concomitant reasonable understanding or appreciation of the fact that the compound* [*will*] *work and in what way.*

Biel v. Chessin, 347 F.2d 898, 902-03 (C.C.P.A. 1965) (Rich, J.) (emphasis added).

DISCUSSION

The court of appeals has interpreted the "conception" component of invention far too loosely, and at variance with the Constitution and the patent code. Further, Federal Circuit precedent is inconsistent and the Executive Branch has taken inconsistent positions as well (indeed, even within this litigation). At bottom, though, this case merits review not so much for these inconsistencies as because the court of appeals has decided wrongly an important issue of federal law. S. Ct. R. 10(c).

The Solicitor General does not dispute that under the fact pattern set out in Barr's reply brief, Ms. *A* is the sole inventor and Dr. *B* has no rights in the invention.[1] *See* Petitioner's Reply Memorandum (No. 94-1527) (Barr

[1] Indeed, although Barr's hypothetical posits only one compound, Barr Reply Mem. 1, the decision of the court of appeals apparently would be the same if a multitude of compounds were involved. *See MacMillan v. Moffett*, 432 F.2d 1237 (C.C.P.A. 1970) (69 compounds). In this case BW selected 113 compounds, submitted 19 (including AZT) to Duke University and the FDA for the unsuccessful testing by those entities, and submitted six to Dr. Broder for testing at the NIH.

Reply Mem.) 1-2. Instead he contends that (assuming one includes the decision Barr is asking this Court to review) the Federal Circuit's conception jurisprudence is internally consistent. U.S. Brief 9-15. Although Barr disagrees, *see* Barr Pet. 16-18; Barr Reply Mem. 4-6, the consistency point is secondary. The primary point is that the Federal Circuit has set the threshold for conception in the area of biological science far below what is envisaged by our patent law.

There are decisions of the Federal Circuit and its predecessors supporting the "reasonable expectation" test, *e.g.*, *Biel*, 347 F.2d 898; *Smith v. Bosquet*, 111 F.2d 157 (C.C.P.A. 1940); *Amax Fly Ash Corp. v. United States*, 514 F.2d 1041, 1048 (Ct. Cl. 1975), and its close relative, simultaneous conception and reduction to practice, *Smith*, 111 F.2d 157; *Alpert v. Slatin*, 305 F.2d 891 (C.C.P.A. 1962). Further, the Solicitor General concedes that "precedents such as *Applegate* [*v. Scherer*, 332 F.2d 571 (C.C.P.A. 1964)] and *MacMillan* [*v. Moffett*, 432 F.2d 1237 (C.C.P.A. 1970)]," which are relied upon by BW, Brief in Opposition (No. 94-1527) 12-13, "hold only that an inventor does not need to *know* that his invention will work," U.S. Brief 12 n. 1 (emphasis in original), and hence do not rule out the reasonable expectation test. He excuses this flaw by claiming that *MacMillan* impliedly is inconsistent with such a test. *Id.* But Barr does not rely on *MacMillan*,[2] which—like the case at bar—invites abuse. Barr Pet. 18.[3] Under

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[2] *Applegate* involved only a single compound, which Scherer had more than a reasonable expectation would work for the intended use. *Applegate*, 332 F.2d at 572.

[3] *MacMillan* is inapposite for another reason: MacMillan was not a coinventor because he " 'was merely conducting standard tests.' " *MacMillan*, 432 F.2d at 1240 (quoting Board of Patent Interferences). Like the Federal Circuit, which conceded that the NIH scientists "exercised considerable skill" and that their testing "necessarily involved interpretation of results for which [the NIH researchers] were *uniquely qualified*," Barr Pet. App. 14a-15a

MacMillan and the decision here, a would-be inventor with any number of chemical compounds on hand—be it sixty-nine, *see MacMillan*, 432 F.2d at 1238, or thirty thousand, *see* Barr Pet. 17; Barr Pet. App. 38a—can select a disease, name each compound in a boilerplate patent application form like BW's, and thereby satisfy the Federal Circuit's conception requirement without even lodging the "applications" anywhere beyond his or her own file room.

When conception supposedly occurred, BW did not believe that the activity of AZT (or of the more than 100 other compounds tested by BW) against murine retroviruses was predictive of activity against the human immunodeficiency virus (HIV). *See* Barr Pet. App. 31a. Indeed, BW concedes that AZT's "potential medical value was not realized until [BW] had the compound tested *in vitro* against the AIDS virus . . . and found it to have especially potent activity against the virus." Fed. Cir. Appendix A5930-31 (1987 affidavit of BW patent agent). That is why BW's scientists could not have had any reasonable expectation that AZT would work against HIV until after receiving the *in vitro* test results from the NIH.

Like the Federal Circuit, the United States has taken inconsistent positions on the conception/joint inventorship issue. In describing the license agreement between the NIH and Barr, U.S. Brief 4, the Solicitor General omits a crucial representation by the government: "[NIH] investigators *conceived and reduced to practice*" the invention. Fed. Cir. Appendix A5386 (Patent License agreement between NIH and Barr, App. D, § 1.01 (July 1991) (emphasis added) (NIH-Barr Agreement)). Barr has been advised that the Department of Justice reviewed and approved the NIH-Barr Agreement before it was executed. Further, NIH previously had told BW that NIH's scientists "should have been named as coinventors" and

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(emphasis added), the Solicitor General concedes that the work of the NIH scientists was anything but "standard," U.S. Brief 8-9.

had requested BW's "cooperation in correcting inventorship." Trial Exh. 2193 (Letter from William Raub, Act'g Dir., NIH, to Philip Tracy, Pres. BW (Dec. 28, 1990)), at 1 (Appendix to this memorandum at 1a). Dr. Raub added that NIH's

> assertion of inventorship rights . . . is consistent with Federal patent law and is the culmination of a thorough review . . . . In reaching our conclusion on inventorship, we carefully reviewed our records of the underlying research collaboration, the various public statements and Congressional testimony of officials of [BW], and the prosecution histories of the relevant U.S. patents. We also conducted a detailed analysis of this case, including consultation with outside patent counsel.

Id. at 2 (App. 2a-3a). Thus the Executive Branch, like the Federal Circuit, is of different minds about what constitutes conception. This is further evidence of the need for review.

The Solicitor General correctly states that the doctrine of simultaneous conception and reduction to practice applies where an inventor is proceeding by trial and error. U.S. Brief 13; *see Alpert*, 305 F.2d at 894. This is because the inventor does not yet have the definite and permanent idea that the law requires. U.S. Brief at 13. He then argues that no such issue is presented here because the draft BW application supplies the requisite evidence of a such an idea. *Id.* 13-14. That contention is incorrect: First, before BW sent AZT to the NIH for testing, researchers at Duke University and the FDA had tested AZT for BW *without positive results*. *See* Barr Pet. 5-6. These experimental failures must have undermined the "fixed" character of any idea on BW's part that AZT would work against AIDS. At a minimum, Barr should have been permitted to adduce evidence on this issue at trial. Second, the all-encompassing, boilerplate character of the draft U.K. application deprives it of any claim to be "definite."

Unable to explain away the "reasonable understanding or appreciation" language of *Biel*, the Solicitor General argues (as did the Federal Circuit) that the statement hasn't been treated as controlling in subsequent cases. U.S. Brief 14. But in 1975 the Court of Claims (a predecessor of the Federal Circuit), citing *Biel*, ruled against a defendant's claim of prior conception of the plaintiff's patented method for controlling abandoned mine fires:

> [I]t is insufficient, on the issue of prior conception, merely to show prior knowledge of the broad idea of hooking up a pneumatic tanker to a borehole extending into a mine cavity. Rather, it must be shown that, in addition to this broad idea, there was a realization, *in finite terms*, of the means or process steps by which the desired result of extinguishing a fire would be achieved.

Amax, 514 F. 2d at 1048 (emphasis added). No other reported citations of *Biel* appear to be with respect to its reasonable expectation aspect. This hardly is evidence that *Biel* was unsound when written or no longer is good law. At most it may suggest that the issue has not come before the Federal Circuit squarely until now.

The Solicitor General chides Barr for citing dictum, U.S. Brief 14, but employs that practice himself in the fruitless quest for a holding of this Court supporting his portion. *The Telephone Cases*, 126 U.S. 1 (1888) (4-3 decision), cited at page 10 of his brief, involved not conception but the other component of invention—reduction to practice. *See id.* at 535-38 ("[I]t is conceded that [Bell] was acting on the right principle and had adopted the true theory").

The Solicitor General disregards the overbroad, boilerplate character of BW's draft U.K. patent application. *See* Barr Reply Mem. 2-4. This goes to whether that application provided the requisite corroboration of BW's claim of conception, which it did not. *See* Barr Pet. App. 13a. In *Meitzner v. Corte*, 410 F.2d 433 (C.C.P.A. 1969),

the inability to appreciate which parameters of the unnamed diluent were particularly significant or how the parameters should be varied to render a given diluent useful was held a failure of conception, *id.* at 438. Similarly, BW's inability to appreciate which route of administration, dosage form, dosage frequency, or dosage size might be effective rendered BW's supposed conception incomplete.

The Solicitor General, U.S. Brief 7, 11, 13, repeats the court of appeals' claim, Barr Pet. App. 13a, that Barr conceded BW's draft U.K. application was an enabling disclosure. Barr did not and does not so concede. This point is important because conception has two elements: formulating a definite and permanent idea *and* corroborating that formulation (e.g., by making "an 'enabling' disclosure—that is, 'a disclosure which would enable a person of ordinary skill in the art' to practice the invention," U.S. Brief 7). Without such corroboration there is no conception, yet the court of appeals permitted a preformatted "disclosure" covering the universe of pharmaceutical delivery options to serve that function. The district court said that Dr. Alexandra Levine, a Barr expert, conceded this point in her deposition. Barr Pet. App. 29a & n. 3. Dr. Levine, who was not a retrovirologist but a clinician treating AIDS patients, *see* Levine Dep. 27, 29, 41-42 (Appendix to this memorandum at 5a-6a), was asked whether she physically *could* have administered AZT to a patient using the universal list of dosage forms, the infinite range of dosage frequencies, and the broad range of dosage amounts set out in the BW U.K. draft application, *id* 55-58 (App. 6a-8a). Dr. Levine pointed out that although she *could* have administered the compound, she *would not* have done so given the high dosages encompassed with the application, *id.* 55-56 (App. 6a-7a), and the absence of any expectation that the drug would work, *id.* 69-71 (App. 8a-10a). When pressed, she stated that she physically *could* administer the drug. *Id.* 57-58 (App. 7a-8a). This is not a concession of enablement or

corroboration. Physicians are the individuals "skilled in the art" where drugs are concerned and, as Dr. Levine testified, no ethical physician would have administered AZT to a human being to treat HIV or AIDS based upon BW's draft U.K. application. *Id.* 69-71 (App. 8a-10a).

It is not enabling to say that if an undetermined amount of one of any number of compounds, prepared using one of the dozen or so recognized dosage forms, is inserted through one of the various bodily orifices (or injected through the skin) an undetermined number of times, the drug will treat HIV. More specificity is necessary, else anyone with a warehouse full of chemicals could designate them all as potential cures for cancer and then "corroborate" the idea or make an "enabling disclosure" by filling in the name and a diagram of each compound in the space provided in BW's boilerplate form. "[W]hen everything is classified, then nothing is classified, and the system becomes one to be disregarded . . . and . . . manipulated." *New York Times Co. v. United States*, 403 U.S. 713, 729 (1971) (Stewart, J., concurring). Similarly, when everything is enabled, nothing is enabled and—as the case at bar demonstrates—comparable mischief is engendered.

The Solicitor General next argues that a low conception threshold will cause no harm because a patent application must clear such other hurdles as utility, novelty, and nonobviousness. *See* U.S. Brief 15-19. If such were the approach of this Court, an unduly low threshold for utility ("not . . . detrimental to the public interest") might have been allowed to stand because an inventor still would need to show conception, novelty, and nonobviousness in order to secure a patent. *See Brenner v. Manson*, 383 U.S. 519 (1966). An unduly low novelty threshold might have endured for similar reasons. *See Great Atlantic & Pacific Tea Co. v. Supermarket Equipment Corp.*, 340 U.S. 147 (1950). In each case, however, this Court examined the relevant criterion and decided that the court of appeals had set the threshold too low.

The Court is cautioned by the Solicitor General that by examining the issue of conception, it might assume a legislative role. U.S. Brief 16. Congress has enacted many patent statutes in the past two centuries but has defined "conception" in none. Indeed, the relevant provisions of the patent code do not even mention conception, 35 U.S.C. §§ 101, 116, and the Federal Circuit noted that Section 116 "does not set forth the minimum quality or quantity of contribution required for joint inventorship." Barr Pet. App. 8a. Moreover, if this Court would be legislating by considering this issue, then the Federal Circuit—over which this Court exercises supervisory authority, *see* S. Ct. R. 10(a)—long has been doing as much.

The Solicitor General questions whether a "reasonable expectation" test for conception in the area of biological science would encourage joint inventorship. *See* U.S. Brief 16. Such a test certainly would do so in this case, and Barr has no reason to doubt that it would do so in other instances as well. Congress has provided deliberately for joint inventorship, adding it to the patent code in 1952, 1 D. CHISUM, PATENTS § 2.02[1] (1995), and expanding it as recently as 1984, Patent Law Amendments Act of 1984, Pub. L. No. 98-622, § 104(a), 98 Stat. 3383, 3384 (codified at 35 U.S.C. § 116).[4] Further, that lawyers might draft around clarifications enunciated by the courts, *see* U.S. Brief 16, hardly is a reason for the latter to forswear clarification. The argument that a reversal might fail to increase competition, U.S. Brief 16-17, suffers from the same shortcomings as that about joint inventorship.

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[4] The 1984 law amended the patent code "to allow inventors to apply for a patent jointly even though (i) they did not physically work together or at the same time, (ii) each did not make the same type or amount of contribution, or (iii) each did not make a contribution to the subject matter of every claim of the patent." 130 Cong. Rec. H10527 (daily ed. Oct. 1, 1984) (analysis of bill).

The Solicitor General's final objection is that "[t]here is no reason to believe . . . that inventors routinely develop documentary evidence of their expectations concerning their inventions' effectiveness." *Id.* 19. In fact, researchers routinely indicate as such and indeed may be required to do so. *E.g.*, 21 C.F.R. § 58.120(a) (FDA rule requiring study protocols to indicate their objectives); *id.* § 58.185(a)(2) (same re reports of study results).

CONCLUSION

For the reasons set forth in the petition, Barr's reply memorandum, and above, the petition for certiorari should be granted.

Respectfully submitted,

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December 1995

APPENDICES

APPENDIX A

[LOGO]

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

December 28, 1990

Philip R. Tracy
President and Chief Executive Officer
Burroughs Wellcome Co.
3030 Cornwallis Road
Research Triangle Park, NC 27709

Dear Mr. Tracy:

As you are aware, the laboratory evaluation and clinical development of AZT as a treatment for HIV infection was the result of a highly successful collaboration among investigators at your company, the National Cancer Institute (NCI) and other institutions. During the course of this collaboration, Burroughs Wellcome filed related patent applications world-wide, and several U.S. patents already have issued that claim AZT-based pharmacautical compositions, as well as the use of AZT to treat AIDS and ARC and to increase the T-lymphocyte count of patients infected with HIV. For the reasons discussed below, we believe that NCI investigators should have been named as coinventors on these patents and request your cooperation in correcting inventorship.

AZT was developed and evaluated by Dr. Jerome Horwitz in 1964, and tested against murine retroviruses in the 1970's. We understand from public statements made by officials of Burroughs Wellcome that its testing of AZT in late 1984 also was limited to non-human animal retroviruses. As Dr. David Barry of Burroughs Wellcome indicated in his letter of March 30, 1987, to Dr. Bruce

Chabner of NCI, activity against such viruses is not considered to be predictive of activity against HIV. Several prior art references cited by the Examiner in the prosecution of Burroughs Wellcome's patents disclose the same tests that apparently were conducted by your company in late 1984. We note that Burroughs Wellcome's patents might be challenged under U.S. patent law if the concept of clinical efficacy against HIV could be extrapolated from studies in non-human test systems.

We understand that in February 1985, when Burroughs Wellcome provided "Compound S" (AZT) to NCI for evaluation, AZT's efficacy against live HIV had not been shown and that investigators at Duke had tried and failed to demonstrate anti-HIV activity. As a matter of patent law, the development of the assay by NCI and its use to test the activity of AZT against HIV at NCI was required to form a "conception" prior to the filing date of Burroughs Wellcome's first relevant British patent application on March 16, 1985. NCI staff also made numerous other contributions to the design and execution of the research collaboration. Thus, NCI investigators should have been named as coinventors on this and subsequent patent applications. The clinical testing in which NCI participated was required to establish a legally sufficient conception at least for some of the patent claims, particularly those directed to increasing T-cell counts.

Our assertion of inventorship rights on behalf of the Department of Health and Human Services is consistent with Federal patent law and is the culmination of a thorough review that was prompted by the Department's more active protection and management of its intellectual property interests following enactment of the Federal Technology Transfer Act of 1986. In reaching our conclusion on inventorship, we carefully reviewed our records of the underlying research collaboration, the various public statements and Congressional testimony of officials of Burroughs Wellcome, and the prosecution histories of the

relevant U. S. patents. We also conducted a detailed analysis of this case, including consultation with outside patent counsel.

We are prepared to discuss the specific facts of this collaboration, as well as the law of inventorship, and we invite Burroughs Wellcome to provide additional facts or legal analysis that you regard as relevant. Mr. Reid G. Adler, Director of the NIH Office of Technology Transfer (301-496-0750), will be pleased to coordinate arrangements for a meeting if you would find that helpful. We fully acknowledge your company's efforts in bringing AZT to market as an AIDS therapeutic and look forward to resolving this matter of inventorship in the near future.

Sincerly yours,

/s/ William F. Raub
WILLIAM F. RAUB, PHD.
Acting Director

cc: Reid G. Adler, J.D.

APPENDIX B

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NORTH CAROLINA
NEW BERN DIVISION

No.: 91-41-CIV-4-H

BURROUGHS WELLCOME CO.,
Plaintiff,

VS.

BARR LABORATORIES, INC.,
Defendant.

No.: 92-134-CIV-4-H

BURROUGHS WELLCOME CO.,
Plaintiff,

VS.

NOVOPHARM, INC.,
Defendant.

AND RELATED CROSS-ACTION.

DEPOSITION OF ALEXANDRA M. LEVINE
Los Angeles, California
April 20, 1993

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* * * *

[27] Q. When you were first contacted by Barr Laboratories' attorneys, were you told that obviousness was an issue in this case?

A. No.

Q. Do you understand what I mean by "obviousness"?

A. No.

Q. That the use of AZT as a treatment for HIV infection was obvious to one skilled in the art—well, withdraw that.

That anybody reviewing the prior literature on AZT would have known that AZT would work as a treatment for HIV infection?

A. Yes. We discussed that.

Q. And what was discussed in that regard?

A. The conversation related to questioning me whether or not I believed as a clinician that there was enough information available with the data on various animal retroviruses to indicate that the same kind of activity might be possible * * *

* * * *

[29] Q. And what did he explain to you in that regard?

A. He explained that in my understanding, the patent law requires that a substance be newly—stop for a minute.

To be patentable, an idea or a product must have a valid basis for believing that it might work in a given circumstance or illness. It has to be something creative in that regard with data to suggest that there was reason to believe, there was reasonable evidence to believe that the new invention or new idea would be active in the disease discussed or system discussed.

Q. Do you have any patents, Dr. Levine?

A. No, I don't.

Q. Have you ever filed any patent applications?

A. No, I haven't.

* * * *

[41] Q. Dr. Levine, what opinions do you intend to render at trial?

A. I intend to state in my opinion, that activity of a given antiretroviral compound, and in this case AZT, in mouse cells using a mouse retrovirus or other animal retroviruses in animal cells would not reasonably be expected to indicate similar activity in human cells or in human retroviral disease.

Q. What is the basis of that opinion, Dr. Levine?

A. The basis of opinion relates to an understanding that human immunodeficiency virus is unique in itself and different from other retroviruses, and that by studying an animal cell and an animal virus, there would be no reasonable belief that that could be directly correlated to a different virus and a different living system.

Q. You are not a retrovirologist, are you, Doctor?

[42] A. I am not.

Q. And you have no expertise in retrovirology?

A. Correct.

Q. But you are going to testify as to the differences between various retroviruses, is that what you are telling me?

A. No. I am going to testify that using a model, for example, of development of cancer drugs, which was the model that I am most familiar with which has been time honored and tested over many decades, it has been clearly demonstrated and shown that in order to determine activity of a given compound in a human, one must, in fact, look at human illness in human lines or in human tumors.

Q. For many years in a cancer context compounds were tested against murine cancers; isn't that correct, Dr. Levine?

A. Yes, it is.

* * * *

[55] Q. —two different pharmaceutical formulations, do you believe that you could have given this to a pharmacist or pharmacologist back in February of 1985 and had the AZT that somebody had previously made to you made into a phamaceutical formulation?

A. Yes. Based on some information later in the document, I believe I could give this to a pharmacologist to make in different formulations.

Q. Okay. And turning to the second page of the draft patent application on the third page of this exhibit document, Bates No. BR083175.

A. Yes.

Q. And refering you to the fourth paragraph down, could you have following the instructions in the fourth paragraph taken this pharmaceutical formulation of AZT and given it to a patient?

A. I most certainly could have, but I would not have. This is way too broad. It includes tremendously high doses and doses that would be [56] very uncomfortable for me. I would not think it appropriate to use this piece of paper to administer, for example, 250 milligrams per kilogram body weight per day.

Q. Well, focusing, Dr. Levine, on the physician's preferable range of 5 to 40 milligrams per kilogram body weight per day, could you, if you wanted to—let's assume for the purposes of this question that you want to administer this pharmaceutical formulation of AZT to a patient.

A. That's a difficult question in the way it is worded. Certainly I could. I could do anything in the world, but I would not automatically use even in the preferred dose 40 milligrams per kilogram body weight per day. I would not do that.

Q. I am not asking you what you would do. I am asking could you follow the directions in this paragraph and administer a pharmaceutical formulation of AZT to a patient following the most preferable dose range of 5 to 40 [57] milligrams, the instructions as to subdosage and the directions as to unit dosage form in the most preferable range of 100 to 400 milligrams of active ingredient per unit dosage form?

A. I could if I had been allowed to do so via an agreement or a statement from the Human Research Committee or the Institutional Review Board.

Q. And if you had chemists make you up some AZT, a pharmacist put that AZT in a chemical formulation and had dosed a patient per the instructions of this document, could you have then measured a patient with HIV infection, could you have then measured whether or not there was a beneficial effect on that patient as a result of administering this compound?

A. I could so determine.

Q. And if you had done all these things, had it made, put in pharmaceutical formulation, given it to a patient with HIV infection, again, using the most preferable range of dosing as laid out in this paragraph, would you have seen [58] a clinical benefit or therapeutic benefit at all? Not optimal therapeutic benefit but any therapeutic benefit?

MR. STUART: Objection as to form. The question is so incredibly broad.

BY MS. MEZEY:

Q. If you could answer the question, Dr. Levine, I would appreciate if you would do so.

A. It depends on the dose that was used. In some of the dosing here, I imagine that I would not have seen a benefit. In other of the dosing I might have seen a benefit.

Q. Okay. Focusing on the 5 to 40 milligrams per kilogram of body weight per day, would you have seen any therapeutic benefit administering 5 milligrams per kilogram of body weight per day?

A. Yes, I believe I would.

Q. And if you had administered 40 milligrams per kilogram of body weight per day, would you have seen some clinical benefit?

* * * *

[69] Q. They knew its half life?

A. Yes.

Q. They had done a whole body radiography of live animals?

A. Uh-huh. Yes.

Q. Now, Dr. Levine, if no HIV screen were available in late 1984 and early 1985, based upon all the information available to BW Co., would you have given this compound to human beings who were dying of HIV infection?

MR. STUART: Objection to form.

THE WITNESS: No, I would not.

BY MS. MEZEY:

Q. Were there any treatments available for HIV infection in late 1984, early 1985?

A. In late 1984 and 1985 there were several compounds that were being studied in human trials. One such compound was Suramin which had, for example, been tested in the human cell [70] system with human HIV prior to use in man, in clinical trials. So that your earlier question, in fact, wasn't the case in late 1984, early 1985. There had been established a human system with HIV.

Q. I understand that. But assuming that there were no such system, there were no treatments for HIV infection, you have all this information about AZT. You have spectacular nanomolar concentration of results in the murine retroviral assay, you have all of this other information, dosing, toxicity, live animal information about AZT, there is nothing out there to treat patients.

Would you have given this to your patients infected with HIV?

A. No. I would not, and I would not have been allowed to do so by the Human Research Committee without data in humans, some sort of human cells or systems that would have allowed them to believe that there was a reason to think there could be activity of that compound in [71] man.

There are many, many compounds that are being given by physicians in the community in desperation related to people who have AIDS. It is going on now, and it was definitely going on in 1984.

For example, the injections of murine into AIDS patients, the use of the Salk polio vaccine in AIDS patients.

There is an entire compendium of drugs or substances which have been used by individuals who believe that this is a desperate situation and, therefore, anything is doable or allowable.

And I don't believe that. I believe that in order to take a human being and experiment with that individual, you must have some valid scientific data to certainly suggest activity in human systems before going into man, have some evidence of activity.

* * * *